MISSOURI BOARD OF PHARMACY

STATUTES & RULES

(March 2024)

Issued By:
Missouri Board of Pharmacy
3605 Missouri Boulevard
P.O. Box 625
Jefferson City, Missouri 65109
(573) 751-0091
Fax: (573) 526-3464
http://pr.mo.gov/pharmacists

This compilation has been provided for informational purposes only and may not include all applicable law. Statutory/rule provisions are subject to change. In the event of a conflict or inconsistency, duly promulgated or enacted state law shall control. Licensees should view the official versions of included state laws/rules to verify current language. The Board expressly reserves the right to revise the contents as deemed appropriate or necessary. Official versions of Missouri laws can be found online at http://www.moga.mo.gov/statutes/statutes.htm . Official versions of state rules are available at http://www.sos.mo.gov/adrules/csr/csr.asp .

Index

Chapter 338, RSMO (Pharmacy Statutes)

Missouri Revised Statutes

Chapter 338

Pharmacists and Pharmacies

September 2023

REGULATION OF PHARMACIES

ELECTRONIC PRIOR AUTHORIZATION COMMITTEE

REGULATION OF WHOLESALE DRUG DISTRIBUTORS

WELL-BEING COMMITTEE

BLOOD CLOTTING THERAPIES

PHARMACY TAX

PHARMACY AUDITS

PHARMACY REBATES FUND

NICOTINE REPLACEMENT THERAPY PRODUCTS

RX CARES FOR MISSOURI PROGRAM

HIV POSTEXPOSURE PROPHYLAXIS

PHARMACISTS

338.010. Practice of pharmacy — license required — auxiliary personnel — written protocol required, when — nonprescription drugs — rulemaking authority — therapeutic plan requirements — veterinarian defined — additional requirements — ShowMeVax system, notice — public health emergencies.

1. The "practice of pharmacy" includes:

(1) The interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353, and the receipt, transmission, or handling of such orders or facilitating the dispensing of such orders;

(2) The designing, initiating, implementing, and monitoring of a medication therapeutic plan in accordance with the provisions of this section;

(3) The compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders;

(4) The ordering and administration of vaccines approved or authorized by the U.S. Food and Drug Administration, excluding vaccines for cholera, monkeypox, Japanese encephalitis, typhoid, rabies, yellow fever, tick-borne encephalitis, anthrax, tuberculosis, dengue, Hib, polio, rotavirus, smallpox, and any vaccine approved after January 1, 2023, to persons at least seven years of age or the age recommended by the Centers for Disease Control and Prevention, whichever is older, pursuant to joint promulgation of rules established by the board of pharmacy and the state board of registration for the healing arts unless rules are established under a state of emergency as described in section 44.100;

(5) The participation in drug selection according to state law and participation in drug utilization reviews;

(6) The proper and safe storage of drugs and devices and the maintenance of proper records thereof;

(7) Consultation with patients and other health care practitioners, and veterinarians and their clients about legend drugs, about the safe and effective use of drugs and devices;

(8) The prescribing and dispensing of any nicotine replacement therapy product under section 338.665;

(9) The dispensing of HIV postexposure prophylaxis pursuant to section 338.730; and

(10) The offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy.

2. No person shall engage in the practice of pharmacy unless he or she is licensed under the provisions of this chapter.

3. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties. This assistance in no way is intended to relieve the pharmacist from his or her responsibilities for compliance with this chapter and he or she will be responsible for the actions of the auxiliary personnel acting in his or her assistance.

4. This chapter shall not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, or podiatry, or veterinary medicine only for use in animals, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220 in the compounding, administering, prescribing, or dispensing of his or her own prescriptions.

5. A pharmacist with a certificate of medication therapeutic plan authority may provide medication therapy services pursuant to a written protocol from a physician licensed under chapter 334 to patients who have established a physician-patient relationship, as described in subdivision (1) of subsection 1 of section 191.1146, with the protocol physician. The written protocol authorized by this section shall come only from the physician and shall not come from a nurse engaged in a collaborative practice arrangement under section 334.104, or from a physician assistant engaged in a collaborative practice arrangement under section 334.735.

6. Nothing in this section shall be construed as to prevent any person, firm or corporation from owning a pharmacy regulated by sections 338.210 to 338.315, provided that a licensed pharmacist is in charge of such pharmacy.

7. Nothing in this section shall be construed to apply to or interfere with the sale of nonprescription drugs and the ordinary household remedies and such drugs or medicines as are normally sold by those engaged in the sale of general merchandise.

8. No health carrier as defined in chapter 376 shall require any physician with which they contract to enter into a written protocol with a pharmacist for medication therapeutic services.

9. This section shall not be construed to allow a pharmacist to diagnose or independently prescribe pharmaceuticals.

10. The state board of registration for the healing arts, under section 334.125, and the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of protocols for medication therapy services. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the protocol physician or similar body authorized by this section, and any other patient protection provisions deemed appropriate by both boards. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither board shall

separately promulgate rules regulating the use of protocols for medication therapy services. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be invalid and void.

11. The state board of pharmacy may grant a certificate of medication therapeutic plan authority to a licensed pharmacist who submits proof of successful completion of a board-approved course of academic clinical study beyond a bachelor of science in pharmacy, including but not limited to clinical assessment skills, from a nationally accredited college or university, or a certification of equivalence issued by a nationally recognized professional organization and approved by the board of pharmacy.

12. Any pharmacist who has received a certificate of medication therapeutic plan authority may engage in the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by a written protocol from a physician that may be specific to each patient for care by a pharmacist.

13. Nothing in this section shall be construed to allow a pharmacist to make a therapeutic substitution of a pharmaceutical prescribed by a physician unless authorized by the written protocol or the physician's prescription order.

14. "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or an equivalent title means a person who has received a doctor's degree in veterinary medicine from an accredited school of veterinary medicine or holds an Educational Commission for Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary Medical Association (AVMA).

15. In addition to other requirements established by the joint promulgation of rules by the board of pharmacy and the state board of registration for the healing arts:

(1) A pharmacist shall administer vaccines by protocol in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC);

(2) A pharmacist who is administering a vaccine shall request a patient to remain in the pharmacy a safe amount of time after administering the vaccine to observe any adverse reactions. Such pharmacist shall have adopted emergency treatment protocols.

16. In addition to other requirements by the board, a pharmacist shall receive additional training as required by the board and evidenced by receiving a certificate from the board upon completion, and shall display the certification in his or her pharmacy where vaccines are delivered.

17. A pharmacist shall inform the patient that the administration of a vaccine will be entered into the ShowMeVax system, as administered by the department of health and senior services. The patient shall attest to the inclusion of such information in the system by signing a form provided by the pharmacist. If the patient indicates that he or she does not want such information entered into the ShowMeVax system, the pharmacist shall provide a written report within fourteen days of administration of a vaccine to the patient's health care provider, if provided by the patient, containing:

(1) The identity of the patient;

(2) The identity of the vaccine or vaccines administered;

(3) The route of administration;

(4) The anatomic site of the administration;

(5) The dose administered; and

(6) The date of administration.

18. A pharmacist licensed under this chapter may order and administer vaccines approved or authorized by the U.S. Food and Drug Administration to address a public health need, as lawfully authorized by the state or federal government, or a department or agency thereof, during a state or federally declared public health emergency.

(RSMo 1939 § 10005, A.L. 1951 p. 737, A.L. 1989 S.B. 39, A.L. 1990 H.B. 1287, A.L. 2007 S.B. 195, A.L. 2009 S.B. 296, A.L. 2011 H.B. 412 merged with S.B. 325, A.L. 2014 S.B. 716 merged with S.B. 754 merged with S.B. 808, A.L. 2017 S.B. 501, A.L. 2018 S.B. 826, A.L. 2019 S.B. 514, A.L. 2021 H.B. 273 merged with H.B. 476, A.L. 2023 H.B. 115 & 99 merged with S.B. 45 & 90 merged with S.B. 157)

Prior revisions: 1929 § 13140; 1919 § 4712; 1909 § 5764

338.012. Medication therapy services, certain diseases, pharmacist may provide under statewide standing order — rulemaking authority.

1. A pharmacist with a certificate of medication therapeutic plan authority may provide influenza, group A streptococcus, and COVID-19 medication therapy services pursuant to a statewide standing order issued by the director or chief medical officer of the department of health and senior services if that person is a licensed physician, or a licensed physician designated by the department of health and senior services.

2. The state board of registration for the healing arts, pursuant to section 334.125, and the state board of pharmacy, pursuant to section 338.140, shall jointly promulgate rules to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become

effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2023, shall be invalid and void.

(L. 2023 H.B. 115 & 99 merged with S.B. 45 & 90 merged with S.B. 157)

338.013. Pharmacy technician to register with board of pharmacy, fees, application, renewal — refusal to issue, when — employee disqualification list maintained, use.

1. Any person desiring to assist a pharmacist in the practice of pharmacy as defined in this chapter shall apply to the board of pharmacy for registration as a pharmacy technician. Such applicant shall be, at a minimum, legal working age and shall forward to the board the appropriate fee and written application on a form provided by the board. Such registration shall be the sole authorization permitted to allow persons to assist licensed pharmacists in the practice of pharmacy as defined in this chapter.

2. The board may refuse to issue a certificate of registration as a pharmacy technician to an applicant that has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, of a violation of any state, territory or federal drug law, or to any felony or has violated any provision of subsection 2 of section 338.055. Alternately, the board may issue such person a registration, but may authorize the person to work as a pharmacy technician provided that person adheres to certain terms and conditions imposed by the board. The board shall place on the employment disqualification list the name of an applicant who the board has refused to issue a certificate of registration as a pharmacy technician, or the name of a person who the board has issued a certificate of registration as a pharmacy technician but has authorized to work under certain terms and conditions. The board shall notify the applicant of the applicant's right to file a complaint with the administrative hearing commission as provided by chapter 621.

3. If an applicant has submitted the required fee and an application for registration to the board of pharmacy, the applicant for registration as a pharmacy technician may assist a licensed pharmacist in the practice of pharmacy as defined in this chapter. The applicant shall keep a copy of the submitted application on the premises where the applicant is employed. If the board refuses to issue a certificate of registration as a pharmacy technician to an applicant, the applicant shall immediately cease assisting a licensed pharmacist in the practice of pharmacy.

4. A certificate of registration issued by the board shall be conspicuously displayed in the pharmacy or place of business where the registrant is employed.

5. Every pharmacy technician who desires to continue to be registered as provided in this section shall, within thirty days before the registration expiration date, file an application for the renewal, accompanied by the fee prescribed by the board. The registration shall lapse and become null and void thirty days after the expiration date.

6. The board shall maintain an employment disqualification list. No person whose name appears on the employment disqualification list shall work as a pharmacy technician, except as otherwise authorized by the board. The board may authorize a person whose name appears on the employment disqualification list to work or continue to work as a pharmacy technician provided the person adheres to certain terms and conditions imposed by the board.

7. The board may place on the employment disqualification list the name of a pharmacy technician who has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, of a violation of any state, territory or federal drug law, or to any felony or has violated any provision of subsection 2 of section 338.055.

8. After an investigation and a determination has been made to place a person's name on the employment disqualification list, the board shall notify such person in writing mailed to the person's last known address:
   (1) That an allegation has been made against the person, the substance of the allegation and that an investigation has been conducted which tends to substantiate the allegation;
   (2) That such person's name has been added in the employment disqualification list of the board;
   (3) The consequences to the person of being listed and the length of time the person's name will be on the list; and
   (4) The person's right to file a complaint with the administrative hearing commission as provided in chapter 621.

9. The length of time a person's name shall remain on the disqualification list shall be determined by the board.

10. No hospital or licensed pharmacy shall knowingly employ any person whose name appears on the employee disqualification list, except that a hospital or licensed pharmacy may employ a person whose name appears on the employment disqualification list but the board has authorized to work under certain terms and conditions. Any hospital or licensed pharmacy shall report to the board any final disciplinary action taken against a pharmacy technician or the voluntary resignation of a pharmacy technician against whom any complaints or reports have been made which might have led to final disciplinary action that can be a cause of action for discipline by the board as provided for in subsection 2 of section 338.055. Compliance with the foregoing sentence may be interposed as an affirmative defense by the employer. Any hospital or licensed pharmacy which reports to the board in good faith shall not be liable for civil damages.

(L. 1997 S.B. 141, A.L. 2004 S.B. 1122, A.L. 2009 S.B. 296)

338.015. Patient's freedom of choice to obtain prescription services, waiver — consultation and advice.

1. The provisions of sections 338.010 to 338.015 shall not be construed to inhibit the patient's freedom of choice to obtain

prescription services from any licensed pharmacist. However, nothing in sections 338.010 to 338.315 abrogates the patient's ability to waive freedom of choice under any contract with regard to payment or coverage of prescription expense.

2. All pharmacists may provide pharmaceutical consultation and advice to persons concerning the safe and therapeutic use of their prescription drugs.

3. All patients shall have the right to receive a written prescription from their prescriber to take to the facility of their choice or to have an electronic prescription transmitted to the facility of their choice.

(L. 1990 H.B. 1287, A.L. 2019 S.B. 514)

(1992) The use of the word "may" in statute permits pharmacist to provide consultation and advice to customers but does not impose duty on pharmacists to monitor customer's use of prescription drugs. Kampe v. Howard Stark Professional Pharmacy Inc., 841 S.W.2d 223 (Mo. App. W.D.).

338.020. Application for license — requirements — examination — oath — penalty — military service, effect of.

1. Every person who shall hereafter desire to be licensed as a pharmacist shall file with the board of pharmacy an application setting forth his name and age, the place, or places, at which and the time spent in the study of the science and art of pharmacy, and the practical experience which the applicant has had under the direction of a legally licensed pharmacist, and shall appear at a time and place designated by the board of pharmacy and submit to an examination as to his qualifications for registration as a licensed pharmacist. Each application shall contain a statement that it is made under oath or affirmation and that its representations are true and correct to the best knowledge and belief of the person signing same, subject to the penalties of making a false affidavit or declaration.

2. So long as the person involved does not represent or hold himself or herself out as a pharmacist licensed to practice in this state, a Missouri pharmacist license shall not be required for a legally qualified pharmacist serving in the Armed Forces of the United States or a legally qualified pharmacist employed by the government of the United States or any bureau, division, or agency thereof who is engaged in the practice of pharmacy while in the discharge of his or her official duties.

(RSMo 1939 § 10006, A.L. 1947 V. I p. 277, A. 1949 H.B. 2075, A.L. 1981 S.B. 16, A.L. 1990 H.B. 1287, A.L. 2014 S.B. 808)
Prior revisions: 1929 § 13141; 1919 § 4713; 1909 § 5765

338.030. Applicant — requirements for qualification.

An applicant for examination shall be twenty-one years of age and in addition shall furnish satisfactory evidence of his good moral character and have had one year practical experience under the supervision of a licensed pharmacist within a licensed pharmacy, or other location approved by the board, and shall be a graduate of a school or college of pharmacy whose requirements for graduation are satisfactory to and approved by the board of pharmacy.

(RSMo 1939 § 10014, A. 1949 H.B. 2075, A.L. 1951 p. 737, A.L. 1981 S.B. 16, A.L. 1990 H.B. 1287, A.L. 2001 H.B. 567)
Prior revisions: 1929 § 13142; 1919 § 4714; 1909 § 5766

338.035. Application, contents — intern pharmacist — board shall promulgate rules, procedure.

1. Every person who desires to be licensed as an intern pharmacist shall file with the board of pharmacy an application, on a form to be provided by the board of pharmacy.

2. If an applicant for an intern pharmacist license has complied with the requirements of this section and with the rules and regulations of the board of pharmacy and is not denied a license on any of the grounds listed in section 338.055, the board of pharmacy may issue to him a license to practice as an intern pharmacist.

3. Any intern pharmacist who wishes to renew his license shall within thirty days before the license expiration date file an application for a renewal.

4. A licensed intern pharmacist may practice pharmacy only under the direct supervision of a pharmacist licensed by the board; provided, however, that an intern pharmacist working at a remote dispensing site pharmacy may be remotely supervised by a pharmacist working at a supervising pharmacy as provided for in section 338.215.

5. The board of pharmacy shall promulgate rules and regulations which shall further regulate the duties of intern pharmacists and shall set the amount of the fees which shall accompany the license and renewal applications for intern pharmacists.

6. No rule or portion of a rule promulgated under the authority of this chapter shall become effective unless it has been promulgated pursuant to the provisions of section 536.024.

(L. 1990 H.B. 1287, A.L. 1993 S.B. 52, A.L. 1995 S.B. 3, A.L. 2007 S.B. 272, A.L. 2020 H.B. 1682)

338.040. License issued without examination, when — reciprocity — equivalency examination — fees.

1. The board of pharmacy shall issue licenses to practice pharmacy in the state without examination to persons who have been legally registered or licensed as pharmacists in other states. Any applicant for a license under this section shall present satisfactory evidence of qualifications equal to those required from licensees in this state, that he was registered or licensed by examination in another state, and that the standard of competence required in the other state is not lower than that required in this state; but no license shall be issued until the board is satisfied that the other state accords similar recognition to the licensees of this state. Applicants for license under this section shall, with their application, forward a fee for

the license as is determined by the board of pharmacy.

2. The board may by rule and regulation require any applicant under subsection 1 of this section to successfully complete any equivalency examination, practical examination, or any examination on Missouri laws pursuant to any rule or regulation as promulgated by the board.

3. Any individual who is registered or licensed in a foreign country may be licensed under the provisions of sections 338.010 to 338.315 upon presentation of satisfactory evidence of qualifications equal to those required of licensees in this state.

4. The board may require any applicant under subsection 3 of this section to successfully complete any equivalency examination, practical examination or any examination on Missouri laws pursuant to any rule and regulation as promulgated by the board.

(RSMo 1939 § 10008, A.L. 1961 p. 501, A.L. 1969 S.B. 390, A.L. 1981 S.B. 16, A.L. 1990 H.B. 1287)
Prior revisions: 1929 § 13144; 1919 § 4716; 1909 § 5768
(1974) Held that standards to be met by applicant for a reciprocal license are the standards that were in effect in this state at the time he was admitted in the state from which he is applying. Missouri State Board of Pharmacy v. Kennedy (A.), 511 S.W.2d 913.

338.043. Temporary license — eligibility — renewal.

1. Notwithstanding any provision of law to the contrary, the board of pharmacy may grant a temporary license to an applicant who meets such requirements as the board may prescribe by rule and regulation.

2. The license shall be renewable at the discretion of and with the approval of the board of pharmacy. A temporary license fee shall accompany the original application for a temporary license and a similar amount shall be paid in the event the temporary license is renewed.

(L. 1990 H.B. 1287, A.L. 1997 S.B. 141, A.L. 2001 H.B. 567)

338.050. Pharmacist license, issued when, period covered.

If the applicant for license as a pharmacist has complied with all the requirements of sections 338.010 and 338.020, the board of pharmacy shall enroll his name upon the register of pharmacists and issue to him a license which shall entitle him to practice as a pharmacist for a period ending with the expiration date of the license.

(RSMo 1939 § 10007, A. 1949 H.B. 2075, A.L. 1961 p. 501, A.L. 1971 S.B. 145, A.L. 1981 S.B. 16)
Prior revisions: 1929 § 13143; 1919 § 4715; 1909 § 5767

338.055. Denial, revocation or suspension of license, grounds for — expedited procedure — temporary authority, when.

1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section or if the designated pharmacist-in-charge, manager-in-charge, or any officer, owner, manager, or controlling shareholder of the applicant has committed any act or practice in subsection 2 of this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621.

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621 against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

(1) Use of any controlled substance, as defined in chapter 195, or alcoholic beverage to an extent that such use impairs a person's ability to perform the work of any profession licensed or regulated by this chapter;

(2) The person has been finally adjudicated and found guilty, or entered a plea of guilty or nolo contendere, in a criminal prosecution under the laws of any state or of the United States, for any offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud, dishonesty or an act of violence, or for any offense involving moral turpitude, whether or not sentence is imposed;

(3) Use of fraud, deception, misrepresentation or bribery in securing any certificate of registration or authority, permit or license issued pursuant to this chapter or in obtaining permission to take any examination given or required pursuant to this chapter;

(4) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation;

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

(7) Impersonation of any person holding a certificate of registration or authority, permit or license or allowing any person to use his or her certificate of registration or authority, permit, license, or diploma from any school;

(8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right

to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, including, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;

(9) A person is finally adjudged incapacitated by a court of competent jurisdiction;

(10) Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter;

(11) Issuance of a certificate of registration or authority, permit or license based upon a material mistake of fact;

(12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder;

(13) Violation of any professional trust or confidence;

(14) Use of any advertisement or solicitation which is false, misleading or deceptive to the general public or persons to whom the advertisement or solicitation is primarily directed;

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;

(16) The intentional act of substituting or otherwise changing the content, formula or brand of any drug prescribed by written, electronic, or oral prescription without prior written or oral approval from the prescriber for the respective change in each prescription; provided, however, that nothing contained herein shall prohibit a pharmacist from substituting or changing the brand of any drug as provided under section 338.056, and any such substituting or changing of the brand of any drug as provided for in section 338.056 shall not be deemed unprofessional or dishonorable conduct unless a violation of section 338.056 occurs;

(17) Personal use or consumption of any controlled substance unless it is prescribed, dispensed, or administered by a health care provider who is authorized by law to do so.

3. After the filing of such complaint, the proceedings shall be conducted in accordance with the provisions of chapter 621. Upon a finding by the administrative hearing commission that the grounds, provided in subsection 2 of this section, for disciplinary action are met, the board may, singly or in combination, censure or place the person named in the complaint on probation on such terms and conditions as the board deems appropriate for a period not to exceed five years, or may suspend, for a period not to exceed three years, or revoke the license, certificate, or permit. The board may impose additional discipline on a licensee, registrant, or permittee found to have violated any disciplinary terms previously imposed under this section or by agreement. The additional discipline may include, singly or in combination, censure, placing the licensee, registrant, or permittee named in the complaint on additional probation on such terms and conditions as the board deems appropriate, which additional probation shall not exceed five years, or suspension for a period not to exceed three years, or revocation of the license, certificate, or permit.

4. If the board concludes that a licensee or registrant has committed an act or is engaging in a course of conduct which would be grounds for disciplinary action which constitutes a clear and present danger to the public health and safety, the board may file a complaint before the administrative hearing commission requesting an expedited hearing and specifying the activities which give rise to the danger and the nature of the proposed restriction or suspension of the licensee's or registrant's license. Within fifteen days after service of the complaint on the licensee or registrant, the administrative hearing commission shall conduct a preliminary hearing to determine whether the alleged activities of the licensee or registrant appear to constitute a clear and present danger to the public health and safety which justify that the licensee's or registrant's license or registration be immediately restricted or suspended. The burden of proving that the actions of a licensee or registrant constitute a clear and present danger to the public health and safety shall be upon the state board of pharmacy. The administrative hearing commission shall issue its decision immediately after the hearing and shall either grant to the board the authority to suspend or restrict the license or dismiss the action.

5. If the administrative hearing commission grants temporary authority to the board to restrict or suspend the licensee's or registrant's license, such temporary authority of the board shall become final authority if there is no request by the licensee or registrant for a full hearing within thirty days of the preliminary hearing. The administrative hearing commission shall, if requested by the licensee or registrant named in the complaint, set a date to hold a full hearing under the provisions of chapter 621 regarding the activities alleged in the initial complaint filed by the board.

6. If the administrative hearing commission dismisses the action filed by the board pursuant to subsection 4 of this section, such dismissal shall not bar the board from initiating a subsequent action on the same grounds.

7. The board shall not deny, revoke, or suspend, or otherwise take any disciplinary action against, a certificate of registration or authority, permit, or license required by this chapter for any person due to the lawful dispensing, distributing, or selling of ivermectin tablets or hydroxychloroquine sulfate tablets for human use in accordance with prescriber directions. A pharmacist shall not contact the prescribing physician or the patient to dispute the efficacy of ivermectin tablets or hydroxychloroquine sulfate tablets for human use unless the physician or patient inquires of the pharmacist about the efficacy of ivermectin tablets or hydroxychloroquine sulfate tablets.

(L. 1971 S.B. 145, A.L. 1978 H.B. 933, A.L. 1981 S.B. 16, A.L. 1986 H.B. 999, A.L. 1998 H.B. 1601, et al., A.L. 2001 H.B. 567, A.L. 2004 S.B. 1122, A.L. 2011 H.B. 412 merged with S.B. 284, A.L. 2019 S.B. 514, A.L. 2022 H.B. 2149)

338.056. Generic substitutions, when, requirements — violations, penalty.

1. Except as provided in subsection 2 of this section, the pharmacist filling prescription orders for drug products prescribed

by trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity and dosage form, and of the same generic drug or interchangeable biological product type, as determined by the United States Adopted Names and accepted by the Federal Food and Drug Administration. Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subsection 2 of this section. The pharmacist who selects the drug or interchangeable biological product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug or biological product as would be incurred in filling a prescription for a drug or interchangeable biological product prescribed by generic or interchangeable biologic name. The pharmacist shall not select a drug or interchangeable biological product pursuant to this section unless the product selected costs the patient less than the prescribed product.

2. A pharmacist who receives a prescription for a brand name drug or biological product may select a less expensive generically equivalent or interchangeable biological product unless:

(1) The patient requests a brand name drug or biological product; or

(2) The prescribing practitioner indicates that substitution is prohibited or displays "brand medically necessary", "dispense as written", "do not substitute", "DAW", or words of similar import on the prescription.

3. No prescription shall be valid without the signature of the prescriber, except an electronic prescription.

4. If an oral prescription is involved, the practitioner or the practitioner's agent, communicating the instructions to the pharmacist, shall instruct the pharmacist as to whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted. The pharmacist shall note the instructions on the file copy of the prescription.

5. Notwithstanding the provisions of subsection 2 of this section to the contrary, a pharmacist may fill a prescription for a brand name drug by substituting a generically equivalent drug or interchangeable biological product when substitution is allowed in accordance with the laws of the state where the prescribing practitioner is located.

6. Violations of this section are infractions.

(L. 1978 H.B. 933, A.L. 1996 H.B. 1237, A.L. 2016 S.B. 875, A.L. 2018 S.B. 826, A.L. 2019 S.B. 514)

338.059. Prescriptions, how labeled.

1. It shall be the duty of a licensed pharmacist or a physician to affix or have affixed by someone under the pharmacist's or physician's supervision a label to each and every container provided to a consumer in which is placed any prescription drug or biological product upon which is typed or written the following information:

(1) The date the prescription is filled;

(2) The sequential number or other unique identifier;

(3) The patient's name;

(4) The prescriber's directions for usage;

(5) The prescriber's name;

(6) The name and address of the pharmacy;

(7) The exact name and dosage of the drug dispensed;

(8) There may be one line under the information provided in subdivisions (1) to (7) of this subsection stating "Refill" with a blank line or squares following or the words "No Refill";

(9) When a generic or interchangeable biological substitution is dispensed, the name of the manufacturer or an abbreviation thereof shall appear on the label or in the pharmacist's records as required in section 338.100.

2. The label of any drug or biological product which is sold at wholesale in this state and which requires a prescription to be dispensed at retail shall contain the name of the manufacturer, expiration date, if applicable, batch or lot number and national drug code.

(L. 1971 S.B. 145, A.L. 1973 S.B. 42, A.L. 1978 H.B. 933, A.L. 1997 S.B. 141, A.L. 2014 S.B. 754 merged with S.B. 808, A.L. 2016 S.B. 875)

338.060. Renewal of license or permit — late renewal or failure to renew, effect — continuing education requirements — inactive license issued when — changed to active, procedure.

1. Every licensed pharmacist or permit holder who desires to continue in the practice of this profession shall, within thirty days before the license expiration date, file an application for the renewal, which application shall be accompanied by the fee prescribed in sections 338.010 to 338.198.

2. If any pharmacist fails, after the expiration of the pharmacist's license, to make application to the board for its renewal, the pharmacist's name shall be removed from the register of licensed pharmacists, and such person, in order to again become registered as a licensed pharmacist, shall be required to pay all delinquent fees. Any pharmacist who fails to renew the pharmacist's license within two years of its expiration and then desires to be preregistered shall be treated in the same manner as a person who has never been licensed. Any registered pharmacist whose certificate of registration has expired while the pharmacist has been engaged in active duty with the United States Army, United States Navy, United States Air Force, the Marine Corps, Coast Guard, or any other branch of the armed services or the state militia called into the service or training of the United States of America, or in training or education under the supervision of the United States preliminary to induction into the military services may have the pharmacist's certificate of registration renewed without paying any lapse,

renewal or registration fee or without passing any examination, if within one year after the termination of such service, training or education, other than by dishonorable discharge, the pharmacist furnishes the board with an affidavit to the effect that the pharmacist has been so engaged and that the pharmacist's service, training or education has terminated.

3. Except as provided in subsection 5 of this section, when applying for a renewal of the license as required by the provisions of this section, each licensed pharmacist shall submit proof of the completion of at least fifteen hours of board-approved continuing education courses during each twelve-month period immediately preceding the date of the application for renewal of the license. The board shall prescribe the form to be completed. No license shall be renewed unless the holder thereof has complied with the provisions of this subsection.

4. The proof of completion of such continuing education shall be in such form as the board may require. The approved courses shall include those offered by correspondence, but the board shall approve all courses of instruction which may be used to satisfy the education requirements of subsection 3 of this section.

5. Each licensed pharmacist may, instead of submitting proof of the completion of the required continuing education courses, apply for an inactive license at the time the pharmacist makes application for the renewal of the pharmacist's license and pay the required renewal fee. An inactive license shall then be issued, and may be renewed biennially. While the inactive license is in effect the pharmacist shall not practice pharmacy. The inactive license may be changed to a regular license without other examination whenever the pharmacist submits proof of the completion of continuing education courses for the total amount of such courses not completed since the pharmacist was last licensed on an active basis.

(RSMo 1939 § 10009, A.L. 1943 p. 521, A.L. 1947 V. I p. 277, A. 1949 H.B. 2075, A.L. 1951 p. 737, A.L. 1981 S.B. 16, A.L. 1984 S.B. 478, A.L. 1997 S.B. 141, A.L. 1999 H.B. 343)
Prior revisions: 1929 § 13145; 1919 § 4717; 1909 § 5769

338.065. Disciplinary hearings — grounds for discipline.

1. At such time as the final trial proceedings are concluded whereby a licensee or registrant, or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit, or license, has been adjudicated and found guilty, or has entered a plea of guilty or nolo contendere, in a felony prosecution pursuant to the laws of the state of Missouri, the laws of any other state, territory, or the laws of the United States of America for any offense reasonably related to the qualifications, functions or duties of a licensee, permittee, or registrant pursuant to this chapter or any felony offense, an essential element of which is fraud, dishonesty or an act of violence, or for any felony offense involving moral turpitude, whether or not sentence is imposed, the board of pharmacy may hold a disciplinary hearing to singly or in combination censure or place the licensee, permittee, or registrant named in the complaint on probation on such terms and conditions as the board deems appropriate for a period not to exceed five years, or may suspend, for a period not to exceed three years, or revoke the license, certificate, registration or permit.

2. Anyone who has been revoked or denied a license, permit or certificate to practice in another state may automatically be denied a license or permit to practice in this state. However, the board of pharmacy may establish other qualifications by which a person may ultimately be qualified and licensed to practice in Missouri.

(L. 1990 H.B. 1287, A.L. 1997 S.B. 141, A.L. 1999 H.B. 343, A.L. 2004 S.B. 1122)

338.067. Revocation and restoration of license — conditions.

1. In any order of revocation, the board may provide that the person may not apply for reinstatement of his license for a period of time ranging from two to seven years following the date of the order of revocation. All stay orders shall toll this time period.

2. Before restoring to good standing a license, certificate or permit issued under sections 338.010 to 338.315 which has been in a revoked, suspended or inactive state for any cause for more than two years, the board may require the applicant to attend such continuing pharmaceutical education courses and pass such examinations as the board may direct.

(L. 1990 H.B. 1287)

338.070. Fees, amount, how set, collection, disposition — fund, created, use, funds transferred to general revenue, when.

1. The board of pharmacy shall set the amount of the fees which this chapter authorizes and requires by rules and regulations promulgated pursuant to chapter 536. The fees shall be set at a level to produce revenue which shall not substantially exceed the cost and expense of administering this chapter. All fees shall be paid before an applicant may be admitted to examination or his or her name placed upon the register of pharmacists, or before any license or permit, or any renewal thereof, is issued by the board.

2. All fees payable pursuant to the provisions of this chapter shall be collected by the division of professional registration and transmitted to the department of revenue for deposit in the state treasury to the credit of the fund to be known as the "Board of Pharmacy Fund".

3. The provisions of section 33.080 to the contrary notwithstanding, money in this fund shall not be transferred and placed to the credit of general revenue until the amount in the fund at the end of the biennium exceeds two times the amount of

the appropriation from the board's funds for the preceding fiscal year or, if the board requires by rule permit renewal less frequently than yearly, then three times the appropriation from the board's funds for the preceding fiscal year. The amount, if any, in the fund which shall lapse is that amount in the fund which exceeds the appropriate multiple of the appropriations from the board's funds for the preceding fiscal year.

(RSMo 1939 § 10015, A.L. 1947 V. I p. 277, A.L. 1953 p. 613, A.L. 1961 p. 501, A.L. 1969 S.B. 390, A.L. 1981 S.B. 16, A.L. 1985 S.B. 99, A.L. 1997 S.B. 141)
Prior revisions: 1929 § 13151; 1919 § 4723; 1909 § 5775

338.075. Adverse actions against licensee, notification to board of pharmacy, when — rulemaking authority.

1. All licensees, registrants, and permit holders of the board of pharmacy shall report to the board of pharmacy:
   (1) Any final adverse action taken by another licensing state, jurisdiction, or government agency against any license, permit, or authorization held by the person or entity to practice or operate as a pharmacist, intern pharmacist, pharmacy technician, pharmacy, drug distributor, drug manufacturer, or drug outsourcing facility. For purposes of this section, "adverse action" shall include, but is not limited to, revocation, suspension, censure, probation, disciplinary reprimand, or disciplinary restriction of a license, permit, or other authorization or a voluntary surrender of such license, permit, or other authorization in lieu of discipline or adverse action;
   (2) Any surrender of a license or authorization to practice or operate as a pharmacist, intern pharmacist, pharmacy technician, pharmacy, drug distributor, drug manufacturer, or drug outsourcing facility while under disciplinary investigation by another licensing state, jurisdiction, or governmental agency; and
   (3) Any exclusion to participate in any state or federally funded health care program such as Medicare, Medicaid, or MO HealthNet for fraud, abuse, or submission of any false or fraudulent claim, payment, or reimbursement request.
2. Reports shall be submitted as provided by the board of pharmacy by rule.
3. The board of pharmacy shall promulgate rules to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2016, shall be invalid and void.

(L. 2016 S.B. 865 & 866)

338.080. Display of license or renewal required.

Every license to practice as a pharmacist, and every permit issued to any person under the provisions of this chapter to establish a pharmacy, and every renewal of such license or permit, shall be conspicuously exposed in the pharmacy or place of business of which the pharmacist or other person to whom it is issued is the owner or manager or in which he is employed.

(RSMo 1939 § 10009, A.L. 1943 p. 521, A.L. 1947 V. I p. 277, A. 1949 H.B. 2075, A.L. 1990 H.B. 1287)
Prior revisions: 1929 § 13145; 1919 § 4717; 1909 § 5769

338.085. Interchangeable biological products, pharmacist may dispense as substitute, when — recordkeeping — rulemaking authority.

1. 1. As used in this chapter, the following terms shall mean:
   (1) "Biological product", the same meaning as such term is defined under 42 U.S.C. Section 262;
   (2) "Interchangeable biological product", a biological product that the Food and Drug Administration:
      (a) Has licensed and determined meets the standards for interchangeability under 42 U.S.C. Section 262(k)(4); or
      (b) Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).
2. A pharmacist may substitute an interchangeable biological product for a prescribed product only if all of the following conditions are met:
   (1) The substituted product has been determined by the Food and Drug Administration to be an interchangeable biological product with the prescribed biological product;
   (2) The substitution occurs according to the provisions of section 338.056; and
   (3) The pharmacy informs the patient of the substitution.
3. Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient including the name of the product and manufacturer. The communication shall be conveyed by making an entry that can be electronically accessed by the prescriber through one of the following means:
   (1) An interoperable electronic medical records system;
   (2) An electronic prescribing technology;
   (3) A pharmacy benefit management system; or

(4) A pharmacy record.

4. Entry into an electronic records system as described in this subsection is presumed to provide notice to the prescriber. Otherwise, if an entry cannot be made under the provisions of subsection 3 of this section, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required if:

(1) There is no Food and Drug Administration approved interchangeable biological product for the product prescribed; or

(2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

5. The pharmacist shall maintain records in a manner consistent with section 338.100.

6. The pharmacist shall label prescriptions in a manner consistent with section 338.059.

7. The board of pharmacy shall maintain a link on its website to the current list of all biological products determined by the Food and Drug Administration to be interchangeable with a specific biological product.

8. The board of pharmacy may promulgate rules for compliance with the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2016, shall be invalid and void.

(L. 2016 S.B. 875)

338.090. Sale of poisons — regulations.

1. It shall be unlawful for any person to retail any poisons enumerated in schedules "A" and "B", except as follows: Schedule "A" arsenic and its preparations, biniodide of mercury, cyanide of potassium, hydrocyanic acid, strychnia, and all other poisonous vegetable alkaloids and their salts, and the essential oil of bitter almonds. Schedule "B" opium and its preparations, except paregoric and other preparations of opium containing less than two grains to the ounce, aconite, bella donna, colchicum, conium, nux vomica, henbane, savin, ergot, cotton root, cantharides, creosote, veratrum, digitalis, and their pharmaceutical preparations, croton oil, chloroform, chloral hydrate, sulphate of zinc, corrosive sublimate, red precipitate, white precipitate, mineral acids, carbolic acid, oxalic acid, without labeling the box, vessel or paper in which the said poison is contained, and also the outside wrapper or cover with the name of the article, the word "poison" and the name and place of business of the seller.

2. Nor shall it be lawful for any person to sell or deliver any poisons enumerated in schedules "A" and "B" unless, upon due inquiry, it is found that the purchaser is aware of its poisonous character and represents that it is to be used for legitimate purposes. Nor shall it be lawful for any registered pharmacists to sell any poisons included in schedule "A" without, before delivering the same to the purchaser, causing an entry to be made in a book kept for that purpose, stating the date of sale, name and address of purchaser, the name of the poison sold, the purpose for which it was represented by the purchaser to be required and the name of the dispenser, such book to be always open for inspection by the proper authorities, and to be preserved for at least five years.

3. The provisions of this section shall not apply to the dispensing of poison in not unusual quantities or doses upon the prescription of practitioners of medicine.

(RSMo 1939 § 10018, A. 1949 H.B. 2075)
Prior revisions: 1929 § 13152; 1919 § 4724; 1909 § 5776
CROSS REFERENCE:
Pesticides registration, 281.210 to 281.310

338.095. Prescription, drug order, defined — telephone prescription, defined — prescription and medical information may be provided, when.

1. The terms "prescription" and "prescription drug order" are hereby defined as a lawful order for medications or devices issued and signed by an authorized prescriber within the scope of his professional practice which is to be dispensed or administered by a pharmacist or dispensed or administered pursuant to section 334.104 to and for the ultimate user. The terms "prescription" and "drug order" do not include an order for medication requiring a prescription to be dispensed, which is provided for the immediate administration to the ultimate user or recipient.

2. The term "telephone prescription" is defined as an order for medications or devices transmitted to a pharmacist by telephone or similar electronic medium by an authorized prescriber or his authorized agent acting in the course of his professional practice which is to be dispensed or administered by a pharmacist or dispensed or administered pursuant to section 334.104 to and for the ultimate user. A telephone prescription shall be promptly reduced to written or electronic medium by the pharmacist and shall comply with all laws governing prescriptions and record keeping.

3. A licensed pharmacist may lawfully provide prescription or medical information to a licensed health care provider or his agent who is legally qualified to administer medications and treatments and who is involved in the treatment of the patient. The information may be derived by direct contact with the prescriber or through a written protocol approved by the prescriber. Such information shall authorize the provider to administer appropriate medications and treatments.

4. Nothing in this section shall be construed to limit the authority of other licensed health care providers to prescribe, administer, or dispense medications and treatments within the scope of their professional practice.

5. It shall be an unauthorized practice of pharmacy and hence unlawful for any person other than the patient or the patient's authorized representative to accept a prescription presented to be dispensed unless that person is located on a premises licensed by the board as a pharmacy.

(L. 1993 H.B. 564, A.L. 2007 S.B. 195)

338.100. Records required to be kept — requirements.

1. Every permit holder of a licensed pharmacy shall cause to be kept in a uniform fashion consistent with this section a suitable book, file, or electronic record-keeping system in which shall be preserved, for a period of not less than five years, the original or order of each drug or biological product which has been compounded or dispensed at such pharmacy, according to and in compliance with standards provided by the board, and shall produce the same in court or before any grand jury whenever lawfully required. A licensed pharmacy may maintain its prescription file on readable microfilm for records maintained over three years. After September, 1999, a licensed pharmacy may preserve prescription files on microfilm or by electronic media storage for records maintained over three years. The pharmacist in charge shall be responsible for complying with the permit holder's record-keeping system in compliance with this section. Records maintained by a pharmacy that contain medical or drug information on patients or their care shall be considered as confidential and shall only be released according to standards provided by the board. Upon request, the pharmacist in charge of such pharmacy shall furnish to the prescriber, and may furnish to the person for whom such prescription was compounded or dispensed, a true and correct copy of the original prescription. The file of original prescriptions kept in any format in compliance with this section, and other confidential records, as defined by law, shall at all times be open for inspection by board of pharmacy representatives. Records maintained in an electronic record-keeping system shall contain all information otherwise required in a manual record-keeping system. Electronic records shall be readily retrievable. Pharmacies may electronically maintain the original prescription or prescription order for each drug or biological product and may electronically annotate any change or alteration to a prescription record in the electronic record-keeping system as authorized by law; provided however, original written and faxed prescriptions shall be physically maintained on file at the pharmacy under state and federal controlled substance laws.

2. An institutional pharmacy located in a hospital shall be responsible for maintaining records of the transactions of the pharmacy as required by federal and state laws and as necessary to maintain adequate control and accountability of all drugs. This shall include a system of controls and records for the requisitioning and dispensing of pharmaceutical supplies where applicable to patients, nursing care units and to other departments or services of the institution. Inspection performed pursuant to this subsection shall be consistent with the provisions of section 197.100.

3. "Electronic record-keeping system", as used in this section, shall mean a system, including machines, methods of organization, and procedures, that provides input, storage, processing, communications, output, and control functions for digitized images of original prescriptions.

(RSMo 1939 § 10019, A.L. 1971 S.B. 145, A.L. 1990 H.B. 1287, A.L. 1997 S.B. 141, A.L. 1999 H.B. 343, A.L. 2010 S.B. 754, A.L. 2016 S.B. 875)
Prior revisions: 1929 § 13153; 1919 § 4725; 1909 § 5777

338.110. Board of pharmacy, members, qualifications, terms.

1. The board of pharmacy shall consist of seven persons not connected with any school of pharmacy. Six members shall be licensed as pharmacists and actively engaged in the practice of pharmacy within this state, and at least one of these shall be a person who provides, on a full-time basis, pharmaceutical services to a hospital, skilled nursing facility or an intermediate care facility. The other member shall be a voting public member. All members shall be appointed by the governor, with the approval of the senate, and shall hold their office for five years from the date of their appointment and until their successors shall have been appointed and qualified.

2. Annually the Missouri Pharmaceutical Association may submit to the director of the division of professional registration the names of five persons licensed as pharmacists within this state, and from this number, or from others, the governor, with the approval of the senate, shall appoint one member to fill the vacancy annually occurring in the board of pharmacy, and vacancies occurring from any other cause shall be filled in like manner. This subsection shall not apply to public member vacancies.

3. The public member shall be at the time of his or her appointment a citizen of the United States; a resident of this state for a period of one year and a registered voter; a person who is not and never was a member of any profession licensed or regulated pursuant to this chapter or the spouse of such person; and a person who does not have and never has had a material, financial interest in either the providing of the professional services regulated by this chapter, or an activity or organization directly related to any profession licensed or regulated pursuant to this chapter. All members, including public members, shall be chosen from lists submitted by the director of the division of professional registration. The duties of the public member shall not include the determination of the technical requirements to be met for licensure or whether any person meets such technical requirements or of the technical competence or technical judgment of a licensee or a candidate for licensure.

(RSMo 1939 § 10010. A. 1949 H.B. 2075. A.L. 1981 S.B. 16. A.L. 1999 H.B. 343)

Prior revisions: 1929 § 13146; 1919 § 4718; 1909 § 5770

338.120. Board of pharmacy — organization.

Annually the board of pharmacy shall organize by the election of a president and vice president who shall hold their offices for one year and until their successors shall have been elected and qualified.

(RSMo 1939 § 10011, A.L. 1981 S.B. 16, A.L. 1997 S.B. 141)
Prior revisions: 1929 § 13147; 1919 § 4719; 1909 § 5771

338.130. Compensation of board members, personnel.

1. Each member of the board shall receive as compensation an amount set by the board not to exceed fifty dollars for each day devoted to the affairs of the board, and shall be entitled to reimbursement of the member's expenses necessarily incurred in the discharge of the member's official duties.
2. The board may employ such board personnel, as defined in subdivision (4) of subsection 11 of section 324.001, as it deems necessary to carry out the provisions of this chapter. The compensation and expenses of such personnel and all expenses incurred by the board in carrying into execution the provisions of this chapter shall be paid out of the board of pharmacy fund upon a warrant on the state treasurer.

(RSMo 1939 § 10017, A. 1949 H.B. 2075, A.L. 1961 p. 503, A.L. 1969 S.B. 390, A.L. 1981 S.B. 16, A.L. 1997 S.B. 141, A.L. 2008 S.B. 788, A.L. 2018 S.B. 975 & 1024 Revision)
Prior revisions: 1929 § 13149; 1919 § 4721; 1909 § 5773

338.132. Board of pharmacy, salary schedule for employees to be established.

Any provision of the law to the contrary notwithstanding, the board of pharmacy shall prepare and maintain an equitable salary schedule for professional staff that are employees of the board. The positions and classification plan for personnel attributed to the inspection of licensed entities within this chapter shall allow for a comparison of such positions with similar positions in adjoining states. Board of pharmacy professional positions shall not be compensated at more than ninety percent parity for corresponding positions within adjoining states for pharmacists employed in those positions.

(L. 2005 S.B. 177 § 1)

338.140. Board of pharmacy, powers, duties — advisory committee, appointment, duties — letters of reprimand, censure or warning.

1. The board of pharmacy shall have a common seal, and shall have power to adopt such rules and bylaws not inconsistent with law as may be necessary for the regulation of its proceedings and for the discharge of the duties imposed pursuant to sections 338.010 to 338.198, and shall have power to employ an attorney to conduct prosecutions or to assist in the conduct of prosecutions pursuant to sections 338.010 to 338.198.
2. The board shall keep a record of its proceedings.
3. The board of pharmacy shall make annually to the governor and, upon written request, to persons licensed pursuant to the provisions of this chapter a written report of its proceedings.
4. The board of pharmacy shall appoint an advisory committee composed of six members, one of whom shall be a representative of pharmacy but who shall not be a member of the pharmacy board, three of whom shall be representatives of wholesale drug distributors as defined in section 338.330, one of whom shall be a representative of drug manufacturers, and one of whom shall be a licensed veterinarian recommended to the board of pharmacy by the board of veterinary medicine. The committee shall review and make recommendations to the board on the merit of all rules and regulations dealing with pharmacy distributors, wholesale drug distributors, drug manufacturers, and veterinary legend drugs which are proposed by the board.
5. A majority of the board shall constitute a quorum for the transaction of business.
6. Notwithstanding any other provisions of law to the contrary, the board may issue letters of reprimand, censure or warning to any holder of a license or registration required pursuant to this chapter for any violations that could result in disciplinary action as defined in section 338.055. Alternatively, at the discretion of the board, the board may enter into a voluntary compliance agreement with a licensee, permit holder, or registrant to ensure or promote compliance with this chapter and the rules of the board, in lieu of board discipline. The agreement shall be a public record. The time limitation identified in section 324.043 for commencing a disciplinary proceeding shall be tolled while an agreement authorized by this section is in effect.

(RSMo 1939 § 10012, A.L. 1981 S.B. 16, A.L. 1989 S.B. 39, A.L. 1997 S.B. 141, A.L. 2011 H.B. 412 merged with S.B. 325, A.L. 2019 S.B. 514)
Prior revisions: 1929 § 13148; 1919 § 4720; 1909 § 5772

338.142. Drug take-back program, board authorized to expend, allocate, or award funds.

The Missouri board of pharmacy, in consultation with the Missouri department of health and senior services, shall be authorized to expend, allocate, or award funds appropriated to the board to private or public entities to develop a drug take-back

program. Such program shall collect and dispose of Schedule II and III controlled substances, as described in section 195.017.

(L. 2017 S.B. 501)

338.143. Technology assisted verification or remote medication dispensing, pilot or demonstration research project authorized — definitions — requirements — expiration date — report.

1. For purposes of this section, the following terms shall mean:
   (1) "Remote medication dispensing", dispensing or assisting in the dispensing of medication outside of a licensed pharmacy;
   (2) "Technology assisted verification", the verification of medication or prescription information using a combination of scanning technology and visual confirmation by a pharmacist.

2. The board of pharmacy may approve, modify, and establish requirements for pharmacy pilot or demonstration research projects related to technology assisted verification or remote medication dispensing that are designed to enhance patient care or safety, improve patient outcomes, or expand access to pharmacy services.

3. To be approved, pilot or research projects shall be within the scope of the practice of pharmacy as defined by chapter 338, be under the supervision of a Missouri licensed pharmacist, and comply with applicable compliance and reporting as established by the board by rule, including any staff training or education requirements. Board approval shall be limited to a period of up to eighteen months, provided the board grant an additional six-month extension if deemed necessary or appropriate to gather or complete research data or if deemed in the best interests of the patient. The board may rescind approval of a pilot project at any time if deemed necessary or appropriate in the interest of patient safety.

*4. The provisions of this subsection shall expire on August 28, 2023. The board shall provide a final report on approved projects and related data or findings to the general assembly on or before December 31, 2022. The name, location, approval dates, general description of and responsible pharmacist for an approved pilot or research project shall be deemed an open record.

(L. 2019 S.B. 514)
**Subsection 4 expires 8-28-23*

338.145. Board president may administer oaths and issue subpoenas — enforcement of subpoenas.

1. The president of the board may, upon majority vote of the board, administer oaths, issue subpoenas duces tecum, and require production of documents and records from any person or entity not licensed by the board when such documents and records are not otherwise available to the board pursuant to the board's inspection authority granted in sections 338.100 and 338.150. Subpoenas duces tecum shall be served by a person authorized to serve subpoenas of courts of record. In lieu of requiring attendance of a person to produce original documents in response to a subpoena duces tecum, the board may require sworn copies of such documents to be filed with it or delivered to its designated representative.

2. The board may enforce its subpoenas duces tecum by applying to the circuit court of Cole County, the county of the investigation, hearing or proceeding, or any county where the records reside or may be found for an order upon any person who shall fail to obey a subpoena duces tecum to show cause why such subpoena duces tecum should not be enforced, which such order and a copy of the application therefor shall be served upon the person in the same manner as a summons in a civil action. If the circuit court shall, after a hearing, determine that the subpoena duces tecum should be sustained and enforced, such court shall proceed to enforce the subpoena duces tecum in the same manner as though the subpoena had been issued in a civil case in the circuit court.

(L. 2004 S.B. 1122)

338.150. Inspections by authorized representatives of board, where — testing program authorized — rulemaking authority.

1. Any person authorized by the board of pharmacy is hereby given the right of entry and inspection upon all open premises purporting or appearing to be drug or chemical stores, apothecary shops, pharmacies or places of business for exposing for sale, or the dispensing or selling of drugs, pharmaceuticals, medicines, chemicals or poisons or for the compounding of physicians' or veterinarians' prescriptions.

2. The board may establish and implement a program for testing drugs or drug products maintained, compounded, filled, or dispensed by licensees, registrants, or permit holders of the board. The board shall pay all testing costs and shall reimburse the licensee, registrant, or permit holder for the reasonable, usual, and customary cost of the drug or drug product requested for testing.

3. The board shall promulgate rules to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2013, shall be invalid and void.

(RSMo 1939 § 10016, A.L. 1951 p. 737, A.L. 1961 p. 503, A.L. 1980 H.B. 1266, A.L. 1981 S.B. 16, A.L. 2011 H.B. 412 merged with S.B. 325, A.L. 2013 H.B. 315 merged with S.B. 306)

338.155. Immunity from civil liability, when.

1. Any person who in good faith and without malice reports, provides information, or cooperates in any manner with the board, or assists the board in any manner including, but not limited to, any applicant or licensee, whether or not the applicant or licensee is the subject of an investigation, record custodians, consultants, attorneys, board members, agents, employees, staff or expert witnesses, in the course of any investigation, hearing or other proceeding conducted by or before the board pursuant to the provisions of this chapter shall not be subject to an action for civil damages as a result of providing such information and cooperating with the board.

2. No physician or other authorized prescriber who, in good faith, cooperates with the board by writing a prescription or drug order at the request of the board pursuant to a routine inspection or a lawful investigation shall, by virtue of that cooperation, be in violation of this chapter or any drug laws of this state and shall be acting as an agent of the state and, as such, shall have sovereign immunity for those actions.

3. No licensee, registrant, permit holder, or other individual or entity subject to the board's jurisdiction who, in good faith, fills a prescription presented by the board as part of an inspection or investigation shall, by virtue of that act, be in violation of this chapter or the drug laws of this state, provided the prescription is otherwise prepared and dispensed in a lawful manner.

(L. 2004 S.B. 1122)

338.165. Class B pharmacies subject to department inspection, when — definitions — rulemaking authority — certificate of medication therapeutic plan authority required, when — dispensing of medications, requirements — advisory committee.

1. As used in this section, the following terms mean:
   (1) "Board", the Missouri board of pharmacy;
   (2) "Hospital", a hospital as defined in section 197.020;
   (3) "Hospital clinic or facility", a clinic or facility under the common control, management, or ownership of the same hospital or hospital system;
   (4) "Medical staff committee", the committee or other body of a hospital or hospital system responsible for formulating policies regarding pharmacy services and medication management;
   (5) "Medication order", an order for a legend drug or device that is:
   (a) Authorized or issued by an authorized prescriber acting within the scope of his or her professional practice or pursuant to a protocol or standing order approved by the medical staff committee; and
   (b) To be distributed or administered to the patient by a health care practitioner or lawfully authorized designee at a hospital or a hospital clinic or facility;
   (6) "Patient", an individual receiving medical diagnosis, treatment or care at a hospital or a hospital clinic or facility.

2. The department of health and senior services shall have sole authority and responsibility for the inspection and licensure of hospitals as provided by chapter 197 including, but not limited to all parts, services, functions, support functions and activities which contribute directly or indirectly to patient care of any kind whatsoever. However, the board may inspect a class B pharmacy or any portion thereof that is not under the inspection authority vested in the department of health and senior services by chapter 197 to determine compliance with this chapter or the rules of the board. This section shall not be construed to bar the board from conducting an investigation pursuant to a public or governmental complaint to determine compliance by an individual licensee or registrant of the board with any applicable provisions of this chapter or the rules of the board.

3. The department of health and senior services shall have authority to promulgate rules in conjunction with the board governing medication distribution and the provision of medication therapy services by a pharmacist at or within a hospital. Rules may include, but are not limited to, medication management, preparation, compounding, administration, storage, distribution, packaging and labeling. Until such rules are jointly promulgated, hospitals shall comply with all applicable state law and department of health and senior services rules governing pharmacy services and medication management in hospitals. The rulemaking authority granted herein to the department of health and senior services shall not include the dispensing of medication by prescription.

4. All pharmacists providing medication therapy services shall obtain a certificate of medication therapeutic plan authority as provided by rule of the board. Medication therapy services may be provided by a pharmacist for patients of a hospital pursuant to a protocol with a physician as required by section 338.010 or pursuant to a protocol approved by the medical staff committee. However, the medical staff protocol shall include a process whereby an exemption to the protocol for a patient may be granted for clinical efficacy should the patient's physician make such request. The medical staff protocol shall also include an appeals process to request a change in a specific protocol based on medical evidence presented by a physician on staff.

5. Medication may be dispensed by a class B hospital pharmacy pursuant to a prescription or a medication order.

6. A drug distributor license shall not be required to transfer medication from a class B hospital pharmacy to a hospital clinic or facility for patient care or treatment.

7. Medication dispensed by a class A pharmacy located in a hospital to a hospital patient for use or administration outside of the hospital under a medical staff-approved protocol for medication therapy shall be dispensed only by a prescription order for medication therapy from an individual physician for a specific patient.

8. Medication dispensed by a hospital to a hospital patient for use or administration outside of the hospital shall be labeled

as provided by rules jointly promulgated by the department of health and senior services and the board including medication distributed for administration by or under the supervision of a health care practitioner at a hospital clinic or facility.

9. This section shall not be construed to preempt any law or rule governing controlled substances.

10. Any rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall only become effective if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly under chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2014, shall be invalid and void.

11. The board shall appoint an advisory committee to review and make recommendations to the board on the merit of all rules and regulations to be jointly promulgated by the board and the department of health and senior services pursuant to the joint rulemaking authority granted by this section. The advisory committee shall consist of:

(1) Two representatives designated by the Missouri Hospital Association, one of whom shall be a pharmacist;

(2) One pharmacist designated by the Missouri Society of Health System Pharmacists;

(3) One pharmacist designated by the Missouri Pharmacy Association;

(4) One pharmacist designated by the department of health and senior services from a hospital with a licensed bed count that does not exceed fifty beds or from a critical access hospital as defined by the department of social services for purposes of MO HealthNet reimbursement;

(5) One pharmacist designated by the department of health and senior services from a hospital with a licensed bed count that exceeds two hundred beds; and

(6) One pharmacist designated by the board with experience in the provision of hospital pharmacy services.

12. Nothing in this section shall be construed to limit the authority of a licensed health care provider to prescribe, administer, or dispense medications and treatments within the scope of their professional practice.

(L. 2014 S.B. 754 merged with S.B. 808)

338.170. Title of pharmacist — used by whom.

It shall be unlawful for any person not legally licensed as a pharmacist to take, use or exhibit the title of pharmacist, or licensed or registered pharmacist, or the title druggist or apothecary, or any other title or description of like import.

(RSMo 1939 § 10020, A.L. 1951 p. 737)
Prior revisions: 1929 § 13154; 1919 § 4726; 1909 § 5778
(1968) Punitive damages were proper in case where it was alleged that defendant who was not registered pharmacist filled prescription without supervision of person who was registered pharmacist. Duensing v. Huscher (Mo.), 431 S.W.2d 169.

338.180. Prosecution of offenders

Upon receiving information that any provision of sections 338.010 to 338.190 has been or is being violated, the secretary of the board of pharmacy shall investigate the matter, and upon probable cause appearing, shall, under the direction of the board, file a complaint and prosecute the offender therefor. It shall be the duty of the prosecuting attorney, upon the request of the secretary, to take charge of and conduct such prosecutions.

(RSMo 1939 § 10013, A. 1949 H.B. 2075)
Prior revisions: 1929 § 13150; 1919 § 4722; 1909 § 5774

338.185. Board has access to certain court records.

After August 28, 1990, notwithstanding any other provisions of law, the board of pharmacy shall have access to records involving an applicant for a license or permit or renewal of a license or permit as provided within this chapter, where the applicant has been adjudicated and found guilty or entered a plea of guilty or nolo contendere in a prosecution under the laws of any state or of the United States for any offense reasonably related to the qualifications, functions, or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud, dishonesty or an act of violence or for any offense involving moral turpitude, whether or not sentence is imposed.

(L. 1990 H.B. 1287)

338.190. Violation of law by licensee — penalty.

Any person who is licensed under this chapter who violates any provision of sections 338.010 to 338.190 shall, upon conviction, be adjudged guilty of a class A misdemeanor.

(RSMo 1939 § 10022, A.L. 1951 p. 737, A.L. 1981 S.B. 16, A.L. 1990 H.B. 1287)
Prior revisions: 1929 § 13156; 1919 § 4728; 1909 § 5780

338.195. Violation of law by person not licensed — penalty.

Any person, who is not licensed under this chapter, who violates any provision of sections 338.010 to 338.315 shall, upon

conviction, be adjudged guilty of a class D felony.

(L. 1990 H.B. 1287, A.L. 2014 S.B. 491)
Effective 1-01-17

338.196. Prescription by practitioner licensed in another state, may be filled, requirement.
Notwithstanding the provisions of section 338.056 to the contrary, a pharmacist may fill a prescription written by a practitioner licensed in a state other than Missouri according to the practitioner's direction as to generic substitution.

(L. 1991 H.B. 444 § 5)

338.198. Pharmacist may fill prescription forwarded by authorized agent.
Other provisions of law to the contrary notwithstanding, a pharmacist may fill a physician's prescription or the prescription of an advanced practice nurse working under a collaborative practice arrangement with a physician, when it is forwarded to the pharmacist by a registered professional nurse or registered physician's assistant or other authorized agent. The written collaborative practice arrangement shall specifically state that the registered professional nurse or registered physician assistant is permitted to authorize a pharmacist to fill a prescription on behalf of the physician.

(L. 1993 H.B. 564)

***338.200. Pharmacist may dispense emergency prescription, when, requirements — rulemaking authority.**
1. In the event a pharmacist is unable to obtain refill authorization from the prescriber due to death, incapacity, or when the pharmacist is unable to obtain refill authorization from the prescriber, a pharmacist may dispense an emergency supply of medication if:
(1) In the pharmacist's professional judgment, interruption of therapy might reasonably produce undesirable health consequences;
(2) The pharmacy previously dispensed or refilled a prescription from the applicable prescriber for the same patient and medication;
(3) The medication dispensed is not a controlled substance;
(4) The pharmacist informs the patient or the patient's agent either verbally, electronically, or in writing at the time of dispensing that authorization of a prescriber is required for future refills; and
(5) The pharmacist documents the emergency dispensing in the patient's prescription record, as provided by the board by rule.
2. (1) If the pharmacist is unable to obtain refill authorization from the prescriber, the amount dispensed shall be limited to the amount determined by the pharmacist within his or her professional judgment as needed for the emergency period, provided the amount dispensed shall not exceed a seven-day supply.
(2) In the event of prescriber death or incapacity or inability of the prescriber to provide medical services, the amount dispensed shall not exceed a thirty-day supply.
3. Pharmacists or permit holders dispensing an emergency supply pursuant to this section shall promptly notify the prescriber or the prescriber's office of the emergency dispensing, as required by the board by rule.
4. An emergency supply may not be dispensed pursuant to this section if the pharmacist has knowledge that the prescriber has otherwise prohibited or restricted emergency dispensing for the applicable patient.
5. The determination to dispense an emergency supply of medication under this section shall only be made by a pharmacist licensed by the board.
6. The board shall promulgate rules to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2013, shall be invalid and void.

(L. 2013 H.B. 315, A.L 2016 S.B. 608 merged with S.B. 635)
*Effective 8-28-16 (S.B. 635); *10-14-16 (S.B. 608), see § 21.250*
**S.B. 608 was vetoed July 5, 2016. The veto was overridden on September 14, 2016.*

338.202. Maintenance medications, pharmacist may exercise professional judgment on quantity dispensed, when.
1. Notwithstanding any other provision of law to the contrary, unless the prescriber has specified on the prescription that dispensing a prescription for a maintenance medication in an initial amount followed by periodic refills is medically necessary, a pharmacist may exercise his or her professional judgment to dispense varying quantities of maintenance medication per fill, up to the total number of dosage units as authorized by the prescriber on the original prescription, including any refills. Dispensing of the maintenance medication based on refills authorized by the physician or prescriber on the prescription shall be limited to no more than a ninety-day supply of the medication, and the maintenance medication shall have been

previously prescribed to the patient for at least a three-month period. The supply limitations provided in this subsection shall not apply if the prescription is issued by a practitioner located in another state according to and in compliance with the applicable laws of that state and the United States or dispensed to a patient who is a member of the United States Armed Forces serving outside the United States.

2. For the purposes of this section, "maintenance medication" is and means a medication prescribed for chronic long-term conditions and that is taken on a regular, recurring basis; except that, it shall not include controlled substances, as defined in and under section 195.010.

(L. 2016 H.B. 1682 merged with H.B. 1816 merged with S.B. 608 merged with S.B. 865 & 866 merged with S.B. 973, A.L. 2018 S.B. 718 merged with S.B. 826)

338.205. Opioid antagonist, storage and dispensing of without a license, when.

1. Notwithstanding any other law or regulation to the contrary, any person or organization acting under a standing order issued by a health care professional who is otherwise authorized to prescribe an opioid antagonist may store an opioid antagonist without being subject to the licensing and permitting requirements of this chapter and may dispense an opioid antagonist if the person does not collect a fee or compensation for dispensing the opioid antagonist.

2. As used in this section, the term "emergency opioid antagonist" means naloxone hydrochloride that blocks the effects of an opioid overdose that is administered in a manner approved by the United States Food and Drug Administration, or any accepted medical practice of administering.

(L. 2016 H.B. 1568)

REGULATION OF PHARMACIES

338.210. Pharmacy defined — practice of pharmacy to be conducted at pharmacy location — rulemaking authority.

1. Pharmacy refers to any location where the practice of pharmacy occurs or such activities are offered or provided by a pharmacist or another acting under the supervision and authority of a pharmacist, including every premises or other place:

(1) Where the practice of pharmacy is offered or conducted;

(2) Where drugs, chemicals, medicines, any legend drugs under 21 U.S.C. Section 353, prescriptions, or poisons are compounded, prepared, dispensed or sold or offered for sale at retail;

(3) Where the words "pharmacist", "apothecary", "drugstore", "drugs", and any other symbols, words or phrases of similar meaning or understanding are used in any form to advertise retail products or services;

(4) Where patient records or other information is maintained for the purpose of engaging or offering to engage in the practice of pharmacy or to comply with any relevant laws regulating the acquisition, possession, handling, transfer, sale or destruction of drugs, chemicals, medicines, prescriptions or poisons;

(5) Where the practice of pharmacy occurs or is offered at a remote dispensing pharmacy site.

2. All activity or conduct involving the practice of pharmacy as it relates to an identifiable prescription or drug order shall occur at the pharmacy location where such identifiable prescription or drug order is first presented by the patient or the patient's authorized agent for preparation or dispensing, unless otherwise expressly authorized by the board.

3. The requirements set forth in subsection 2 of this section shall not be construed to bar the complete transfer of an identifiable prescription or drug order pursuant to a verbal request by or the written consent of the patient or the patient's authorized agent.

4. The board is hereby authorized to enact rules waiving the requirements of subsection 2 of this section and establishing such terms and conditions as it deems necessary, whereby any activities related to the preparation, dispensing or recording of an identifiable prescription or drug order may be shared between separately licensed facilities.

5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation.

6. Nothing in this section shall be construed to supersede the provisions of section 197.100.

(L. 1951 p. 734 § 1(a), A.L. 2001 H.B. 567, A.L. 2011 H.B. 412 merged with S.B. 325, A.L. 2020 H.B. 1682)

338.215. Remote dispensing site pharmacy — definitions — requirements — supervision — location — staffing — license required, when — rulemaking authority.

1. For purposes of this section, the following terms mean:

(1) "Remote dispensing site pharmacy", any location in this state where the practice of pharmacy occurs and that is licensed as a pharmacy to dispense prescription drugs and is staffed by one or more qualified pharmacy technicians, as defined by the board, or intern pharmacists, whose activities are supervised by a pharmacist at a supervising pharmacy through a continuous real-time audio and video link. "Remote dispensing site pharmacy" does not include the office of a dispensing prescriber or an automated device;

(2) “Supervising pharmacy”, a pharmacy licensed in this state under the provisions of this chapter that oversees the dispensation activities of a remote dispensing site pharmacy.

2. A supervising pharmacy that operates a remote dispensing site pharmacy, and the remote dispensing site pharmacy, shall be licensed as a pharmacy by the board of pharmacy. The board shall issue a license to a remote dispensing site pharmacy that meets the requirements of this subsection. The remote dispensing site pharmacy shall:

(1) Submit an application and pay the licensing fee established by the board;

(2) Be jointly owned by a supervising pharmacy; and

(3) Maintain a policy and procedures manual that includes the following:

(a) A description of how the supervising pharmacy and remote dispensing site pharmacy will comply with federal and state laws, rules, and regulations;

(b) The procedure for the supervising pharmacy to supervise the remote dispensing site pharmacy and counsel patients in accordance with the laws of this state prior to the dispensing of a prescription drug under this section;

(c) The procedure for reviewing the prescription drug inventory and drug records maintained by the remote dispensing site pharmacy;

(d) The policy and procedure for providing appropriate security to protect the confidentiality and integrity of patient information;

(e) The written plan for recovery from an event that interrupts or prevents a pharmacist from supervising the operation of the remote dispensing site pharmacy;

(f) The specific duties, tasks, and functions that a registered pharmacy technician or intern pharmacist is authorized to perform at the remote dispensing site pharmacy under the remote supervision of a licensed pharmacist at the supervising pharmacy; and

(g) The procedure for maintaining an up-to-date inventory of all controlled substances.

3. A remote dispensing site pharmacy shall be under the supervision and control of a supervising pharmacist employed by the supervising pharmacy. The supervising pharmacist shall not be required to be immediately physically present to supervise activities at the remote dispensing site pharmacy, but shall make monthly visits to the remote dispensing site pharmacy in order to ensure compliance with this section.

4. A supervising pharmacist and a remote dispensing site pharmacy shall share common ownership. A pharmacist shall neither be designated nor act as a supervising pharmacist for more than two remote dispensing site pharmacies at one time.

5. A pharmacist at the supervising pharmacy shall verify each prescription before it leaves the remote dispensing site pharmacy. Verification shall occur through the use of technology that includes bar coding and visual review via remote video. As applicable, a pharmacist, intern pharmacist, and pharmacy technician’s initials or unique identifier shall appear in the prescription record to identify the name and specific activities of each pharmacist, intern pharmacist, or pharmacy technician involved in the dispensing process.

6. Unless a pharmacist is onsite at the remote dispensing site pharmacy, counseling shall be done by a supervising pharmacist at the supervising pharmacy via a HIPAA-compliant continuous real-time video and audio link before a drug or medical device is released to the patient. The system being used to perform the consultation shall retain the initials or unique identifier of the pharmacist who performs the consultation. The pharmacist providing counseling under this subsection shall be employed by and located at the supervising pharmacy and have access to all relevant patient information maintained by the remote dispensing site pharmacy.

7. A remote dispensing site pharmacy shall be located at least ten miles from an existing retail pharmacy unless:

(1) The remote dispensing site pharmacy is part of a community mental health center, federally qualified health center, rural health clinic, or outpatient clinic setting; or

(2) An applicant of a proposed remote dispensing site pharmacy demonstrates to the board how the proposed remote dispensing site pharmacy will promote public health.

8. The remote dispensing pharmacy shall be staffed by a pharmacist at least eight hours a month and shall reconcile the up-to-date controlled substance inventory twice a month. The supervising pharmacist may provide services as allowed in section 338.010 and as provided by policies and procedures.

9. If the average number of prescriptions dispensed per day by the remote dispensing site pharmacy exceeds one hundred fifty prescriptions, the remote dispensing site pharmacy shall, within ten days, apply to the board for licensure as a class A, B, or C pharmacy, as applicable. The average number of prescriptions dispensed per day shall be determined by averaging the number of prescriptions dispensed per day over the previous ninety-day period.

10. Unless otherwise approved by the board, the supervising pharmacy shall be located in this state and within fifty road miles of a remote dispensing site pharmacy to ensure that the remote dispensing site pharmacy is sufficiently supported by the supervising pharmacy and that necessary personnel or supplies may be delivered to the remote dispensing site pharmacy within a reasonable period of time of an identified need.

11. The board of pharmacy may promulgate all necessary rules and regulations for the implementation of this section, provided that no such rules and regulations shall restrict the practice of pharmacy at a remote dispensing site pharmacy. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant

to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2020, shall be invalid and void.

(L. 2020 H.B. 1682)

338.220. Operation of pharmacy without permit or license unlawful — application for permit, classifications, fee — duration of permit.

1. It shall be unlawful for any person, copartnership, association, corporation or any other business entity to open, establish, operate, or maintain any pharmacy as defined by statute without first obtaining a permit or license to do so from the Missouri board of pharmacy. A permit shall not be required for an individual licensed pharmacist to perform nondispensing activities outside of a pharmacy, as provided by the rules of the board. A permit shall not be required for an individual licensed pharmacist to administer drugs, vaccines, and biologicals by protocol, as permitted by law, outside of a pharmacy. The following classes of pharmacy permits or licenses are hereby established:

(1) Class A: Community/ambulatory;
(2) Class B: Hospital pharmacy;
(3) Class C: Long-term care;
(4) Class D: Nonsterile compounding;
(5) Class E: Radio pharmaceutical;
(6) Class F: Renal dialysis;
(7) Class G: Medical gas;
(8) Class H: Sterile product compounding;
(9) Class I: Consultant services;
(10) Class J: Shared service;
(11) Class K: Internet;
(12) Class L: Veterinary;
(13) Class M: Specialty (bleeding disorder);
(14) Class N: Automated dispensing system (health care facility);
(15) Class O: Automated dispensing system (ambulatory care);
(16) Class P: Practitioner office/clinic;
(17) Class Q: Charitable pharmacy; and
(18) Class R: Remote dispensing site pharmacy.

2. Application for such permit or license shall be made upon a form furnished to the applicant; shall contain a statement that it is made under oath or affirmation and that its representations are true and correct to the best knowledge and belief of the person signing same, subject to the penalties of making a false affidavit or declaration; and shall be accompanied by a permit or license fee. The permit or license issued shall be renewable upon payment of a renewal fee. Separate applications shall be made and separate permits or licenses required for each pharmacy opened, established, operated, or maintained by the same owner.

3. All permits, licenses or renewal fees collected pursuant to the provisions of sections 338.210 to 338.370 shall be deposited in the state treasury to the credit of the Missouri board of pharmacy fund, to be used by the Missouri board of pharmacy in the enforcement of the provisions of sections 338.210 to 338.370, when appropriated for that purpose by the general assembly.

4. Class L: veterinary permit shall not be construed to prohibit or interfere with any legally registered practitioner of veterinary medicine in the compounding, administering, prescribing, or dispensing of their own prescriptions, or medicine, drug, or pharmaceutical product to be used for animals.

5. Except for any legend drugs under 21 U.S.C. Section 353, the provisions of this section shall not apply to the sale, dispensing, or filling of a pharmaceutical product or drug used for treating animals.

6. A "class B hospital pharmacy" shall be defined as a pharmacy owned, managed, or operated by a hospital as defined by section 197.020 or a clinic or facility under common control, management or ownership of the same hospital or hospital system. This section shall not be construed to require a class B hospital pharmacy permit or license for hospitals solely providing services within the practice of pharmacy under the jurisdiction of, and the licensure granted by, the department of health and senior services under and pursuant to chapter 197.

7. Upon application to the board, any hospital that holds a pharmacy permit or license on August 28, 2014, shall be entitled to obtain a class B pharmacy permit or license without fee, provided such application shall be submitted to the board on or before January 1, 2015.

(L. 1951 p. 734 § 1, A.L. 1969 S.B. 390, A.L. 1981 S.B. 16, A.L. 1989 S.B. 39, A.L. 1997 S.B. 141, A.L. 1999 H.B. 343, A.L. 2001 H.B. 567, A.L. 2004 S.B. 1122, A.L. 2007 H.B. 780 merged with S.B. 272, A.L. 2009 S.B. 296, A.L. 2011 H.B. 412 merged with S.B. 325, A.L. 2013 H.B. 315, A.L. 2014 S.B. 754 merged with S.B. 808, A.L. 2020 H.B. 1682 merged with H.B. 2046)

338.230. Disposition of fees

All fees collected under the provisions of sections 338.210 to 338.370 shall be deposited in the state treasury to the credit of the Missouri board of pharmacy fund, to be used by the Missouri board of pharmacy in the enforcement of the provisions

of sections 338.210 to 338.370, when appropriated for that purpose by the general assembly.

(L. 1951 p. 734 § 3, A.L. 1989 S.B. 39)

338.240. Evidence required for issuance of permit — veterinary permit pharmacy, designation of supervising registered pharmacist, when.

1. Upon evidence satisfactory to the said Missouri board of pharmacy:
   (1) That the pharmacy for which a permit, or renewal thereof, is sought, will be conducted in full compliance with sections 338.210 to 338.300, with existing laws, and with the rules and regulations as established hereunder by said board;
   (2) That the equipment and facilities of such pharmacy are such that it can be operated in a manner not to endanger the public health or safety;
   (3) That such pharmacy is equipped with proper pharmaceutical and sanitary appliances and kept in a clean, sanitary and orderly manner;
   (4) That the management of said pharmacy is under the supervision of either a registered pharmacist, or an owner or employee of the owner, who has at his or her place of business a registered pharmacist employed for the purpose of compounding physician's or veterinarian's prescriptions in the event any such prescriptions are compounded or sold;
   (5) That said pharmacy is operated in compliance with the rules and regulations legally prescribed with respect thereto by the Missouri board of pharmacy, a permit or renewal thereof shall be issued to such persons as the said board of pharmacy shall deem qualified to conduct such pharmacy.
2. In lieu of a registered pharmacist as required by subdivision (4) of subsection 1 of this section, a pharmacy permit holder that only holds a class L veterinary permit and no other pharmacy permit may designate a supervising registered pharmacist who shall be responsible for reviewing the activities and records of the class L pharmacy permit holder as established by the board by rule. The supervising registered pharmacist shall not be required to be physically present on site during the business operations of a class L pharmacy permit holder identified in subdivision (5) of subsection 1 of this section when noncontrolled legend drugs under 21 U.S.C. Section 353 are being dispensed for use in animals, but shall be specifically present on site when any noncontrolled drugs for use in animals are being compounded.

(L. 1951 p. 734 § 2, A.L. 2011 H.B. 412 merged with S.B. 325)

338.250. Equipment required — manner of operation of pharmacy — compliance with state and federal laws required.

No pharmacy shall be licensed under the provisions of this chapter unless it is equipped with proper pharmaceutical equipment and reference manuals, so that the practice of pharmacy may be accurately and properly performed. The board shall prescribe the minimum of technical equipment which the pharmacy shall at all times possess. Such requirements may vary, depending upon the population served, but shall be consistently and uniformly enforced. No permit shall be issued or renewed for the operation of a pharmacy unless the pharmacy shall be operated in a manner and according to the rules and regulations prescribed by law and by the Missouri board of pharmacy with respect to obtaining and maintaining such a permit. Any pharmacy that receives or possesses drugs or devices shall be held responsible for compliance with all laws within this chapter as well as state and federal drug laws on all drugs received or possessed, including but not limited to drugs and devices received or possessed pursuant to a consignment arrangement.

(L. 1951 p. 734 § 6, A.L. 1990 H.B. 1287, A.L. 1998 S.B. 940)

338.255. Specific prescription or nonprescription drugs or devices, no requirement to carry.

Notwithstanding any other provision of law, no pharmacy licensed in this state shall be required to carry or maintain in inventory any specific prescription or nonprescription drug or device.

(L. 2013 S.B. 126)

338.260. Business name not to include certain words unless supervised by pharmacist — historical names permitted — board of pharmacy may enforce — remote dispensing site pharmacy, physical presence of pharmacist not required, when.

1. No person shall carry on, conduct or transact a business under a name which contains as part of the name the words "pharmacist", "pharmacy", "apothecary", "apothecary shop", "chemist shop", "drug store", "druggist", "drugs", "consultant pharmacist", or any word of similar or like import, unless the place of business is supervised by a licensed pharmacist.
2. Nothing in this chapter shall be construed to prevent any person from using a historical name in reference to any building, structure, or business so long as the person is not engaged in the practice of pharmacy as defined in section 338.010.
3. Notwithstanding the provisions of subsection 2 of this section, the board of pharmacy shall retain authority to enforce the provisions of subsection 1 of this section against any person offering for sale any naturopathic or homeopathic service or any herbal, nutritional, vitamin, dietary, mineral, or other supplement intended for human application, absorption, or consumption.
4. Supervision of a licensed remote dispensing site pharmacy shall not require a pharmacist to be physically present at the remote dispensing site pharmacy location, provided that dispensing activities are supervised by a supervising pharmacist located at a Missouri-licensed supervising pharmacy through the use of a continuous real-time audio and video link.

(L. 1951 p. 737 § 338.170, A.L. 1990 H.B. 1287, A.L. 2009 S.B. 394, A.L. 2020 H.B. 1682)

338.270. Renewal applications to be made, when.

1. Application blanks for renewal permits shall be mailed to each permittee on or before the first day of the month in which the permit expires and, if application for renewal of permit is not made before the first day of the following month, the existing permit, or renewal thereof, shall lapse and become null and void upon the last day of that month.

2. The board of pharmacy shall not renew a nonresident pharmacy license if the renewal applicant does not hold a current pharmacy license or its equivalent in the state in which the nonresident pharmacy is located.

(L. 1951 p. 734 § 3, A.L. 1981 S.B. 16, A.L. 2016 S.B. 865 & 866)

338.280. Board of pharmacy, rules and regulations.

The Missouri board of pharmacy may make such rules and regulations, not inconsistent with law, as may be necessary to carry out the purposes and enforce the provisions of sections 338.210 to 338.300.

(L. 1951 p. 734 § 4, A.L. 1971 S.B. 145, A.L. 1981 S.B. 16)
(1987) Board of Pharmacy has no jurisdiction to regulate pharmacies in hospitals. Missouri Hospital Association v. Department of Consumer Affairs, Regulation and Licensing. 731 S.W.2d 262 (Mo.App.).
(1987) This section does not give the Board of Pharmacy the authority or jurisdiction to promulgate rules and regulations regarding in-hospital dispensing of drugs. Missouri Hospital Association v. Missouri Department of Consumer Affairs, Regulation and Licensing. 731 S.W.2d 262 (Mo.App.).

338.285. Board may file complaint, when, where filed.

The board is hereby authorized and empowered, when examination or inspection of a pharmacy shall disclose to the board that the pharmacy is not being operated or conducted according to such legal rules and regulations and the laws of Missouri with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621 charging the holder of a permit to operate a pharmacy with conduct constituting grounds for discipline in accordance with section 338.055.

(L. 1971 S.B. 145, A.L. 2001 H.B. 567)

338.290. Appeals from decision of board, notice of right.

Any person denied a permit to establish or operate a pharmacy, or renewal of such permit, may appeal the decision of the board of pharmacy in the manner provided by law, and shall be notified of this right at the time of denial.

(L. 1951 p. 734 § 5, A.L. 1981 S.B. 16)

338.300. Permit to be posted — not transferable.

The permit, or renewal thereof, issued under the provisions of sections 338.210 to 338.300, and under which a pharmacy is being operated, shall be posted and exposed in a conspicuous place in such pharmacy; such permit or renewal of permit shall not be transferable.

(L. 1951 p. 734 § 3, A.L. 1981 S.B. 16)

338.310. Violation, a misdemeanor.

Every person who violates any provision of sections 338.210 to 338.300 shall, upon conviction thereof, be adjudged guilty of a class C misdemeanor.

(L. 1951 p. 734 § 7, A.L. 1981 S.B. 16)

338.314. Inspection of pharmacy within certain facilities authorized — applicability of law.

Nothing in sections 338.010 to 338.315 shall authorize the board of pharmacy to conduct an inspection of a long-term care facility licensed under the provisions of chapter 198 by the Missouri department of health and senior services, except that the board of pharmacy may inspect any licensed pharmacy located within a long-term care facility. However, the provisions of sections 338.010 to 338.315 shall apply to all individuals licensed as a pharmacist and practicing pharmacy as defined in section 338.010.

(L. 1990 H.B. 1287, A.L. 2014 H.B. 1299 Revision)

338.315. Receipt of drugs from unlicensed source, unlawful — penalty — pharmacy-to-pharmacy transfers, limit — legend drugs, inventories and records — rulemaking authority.

1. Except as otherwise provided by the board by rule, it shall be unlawful for any pharmacist, pharmacy owner or person employed by a pharmacy to knowingly purchase or receive any legend drugs under 21 U.S.C. Section 353 from other than a licensed or registered drug distributor, drug outsourcer, third-party logistics provider, or licensed pharmacy. Any person who violates the provisions of this section shall, upon conviction, be adjudged guilty of a class A misdemeanor. Any subsequent

conviction shall constitute a class E felony.

2. Notwithstanding any other provision of law to the contrary, the sale, purchase, or trade of a prescription drug by a pharmacy to other pharmacies is permissible if the total dollar volume of such sales, purchases, or trades are in compliance with the rules of the board and do not exceed five percent of the pharmacy's total annual prescription drug sales.

3. Pharmacies shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of legend drugs. Such records shall be maintained for two years and be readily available upon request by the board or its representatives.

4. The board shall promulgate rules to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2012, shall be invalid and void.

(L. 1989 S.B. 39, A.L. 2011 S.B. 325, A.L. 2012 H.B. 1563, A.L. 2014 S.B. 491, A.L. 2018 H.B. 1719)

ELECTRONIC PRIOR AUTHORIZATION COMMITTEE

338.320. Committee established, purpose, members, duties — sunset provision.

1. There is hereby established the "Missouri Electronic Prior Authorization Committee" in order to facilitate, monitor, and report to the general assembly on Missouri-based efforts to contribute to the establishment of national electronic prior authorization standards. Such efforts shall include the Missouri-based electronic prior authorization pilot program established under subsection 5 of this section and the study and dissemination of information by the committee of the efforts of the National Council on Prescription Drug Programs (NCPDP) to develop national electronic prior authorization standards. The committee shall advise the general assembly and the department of commerce and insurance as to whether there is a need for administrative rules to be promulgated by the department of commerce and insurance as soon as practically possible.

2. The Missouri electronic prior authorization committee shall consist of the following members:

(1) Two members of the senate, appointed by the president pro tempore of the senate;

(2) Two members of the house of representatives, appointed by the speaker of the house of representatives;

(3) One member from an organization of licensed physicians in the state;

(4) One member who is a physician licensed in Missouri pursuant to chapter 334;

(5) One member who is a representative of a Missouri pharmacy benefit management company;

(6) One member from an organization representing licensed pharmacists in the state;

(7) One member from the business community representing businesses on health insurance issues;

(8) One member from an organization representing the leading research-based pharmaceutical and biotechnology companies;

(9) One member from an organization representing the largest generic pharmaceutical trade association;

(10) One patient advocate;

(11) One member from an electronic prescription network that facilitates the secure electronic exchange of clinical information between physicians, pharmacies, payers, and pharmacy benefit managers and other health care providers;

(12) One member from a Missouri-based electronic health records company;

(13) One member from an organization representing the largest number of hospitals in the state;

(14) One member from a health carrier as such term is defined under section 376.1350;

(15) One member from an organization representing the largest number of health carriers in the state, as such term is defined under section 376.1350;

(16) The director of the department of social services, or the director's designee;

(17) The director of the department of commerce and insurance, who shall be chair of the committee.

3. All of the members, except for the members from the general assembly, shall be appointed by the governor no later than September 1, 2012, with the advice and consent of the senate. The staff of the department of commerce and insurance shall provide assistance to the committee.

4. The duties of the committee shall be as follows:

(1) Before February 1, 2019, monitor and report to the general assembly on the Missouri-based electronic prior authorization pilot program created under subsection 5 of this section including a report of the outcomes and best practices developed as a result of the pilot program and how such information can be used to inform the national standard-setting process;

(2) Obtain specific updates from the NCPDP and other pharmacy benefit managers and vendors that are currently engaged in pilot programs working toward national electronic prior authorization standards;

(3) Correspond and collaborate with the NCPDP and other such pilots through the exchange of information and ideas;

(4) Assist, when asked by the pharmacy benefit manager, with the development of the pilot program created under

subsection 5 of this section with an understanding of information on the success and failures of other pilot programs across the country;

(5) Prepare a report at the end of each calendar year to be distributed to the general assembly and governor with a summary of the committee's progress and plans for the next calendar year, including a report on Missouri-based efforts to contribute to the establishment of national electronic prior authorization standards. Such annual report shall continue until such time as the NCPDP has established national electronic prior authorization standards or this section has expired, whichever is sooner. The first report shall be completed before January 1, 2013;

(6) Upon the adoption of national electronic prior authorization standards by the NCPDP, prepare a final report to be distributed to the general assembly and governor that identifies the appropriate Missouri administrative regulations, if any, that will need to be promulgated by the department of commerce and insurance, in order to make those standards effective as soon as practically possible, and advise the general assembly and governor if there are any legislative actions necessary to the furtherance of that end.

5. The department of commerce and insurance and the Missouri electronic prior authorization committee shall recruit a Missouri-based pharmacy benefits manager doing business nationally to volunteer to conduct an electronic prior authorization pilot program in Missouri. The pharmacy benefits manager conducting the pilot program shall ensure that there are adequate Missouri licensed physicians and an electronic prior authorization vendor capable and willing to participate in a Missouri-based pilot program. Such pilot program established under this section shall be operational by January 1, 2014. The department and the committee may provide advice or assistance to the pharmacy benefit manager conducting the pilot program but shall not maintain control or lead with the direction of the pilot program.

6. Pursuant to section 23.253 of the Missouri sunset act:

(1) The provisions of the new program authorized under this section shall sunset automatically six years after August 28, 2012, unless reauthorized by an act of the general assembly; and

(2) If such program is reauthorized, the program authorized under this section shall sunset automatically twelve years after the effective date of the reauthorization of this section; and

(3) This section shall terminate on September first of the calendar year immediately following the calendar year in which the program authorized under this section is sunset.

(L. 2012 H.B. 1563 merged with H.B. 1827)

REGULATION OF WHOLESALE DRUG DISTRIBUTORS

338.330. Definitions.

As used in sections 338.300 to 338.370, the following terms mean:

(1) "Drug outsourcer", an outsourcing facility as defined by 21 U.S.C. Section 353b of the federal Drug Quality and Security Act;

(2) "Legend drug":

(a) Any drug or biological product:

a. Subject to Section 503(b) of the Federal Food, Drug and Cosmetic Act, including finished dosage forms and active ingredients subject to such Section 503(b); or

b. Required under federal law to be labeled with one of the following statements prior to being dispensed or delivered:

(i) "Caution: Federal law prohibits dispensing without prescription";

(ii) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(iii) "Rx Only"; or

c. Required by any applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use or dispensed by practitioners only; and

(b) The term "drug", "prescription drug", or "legend drug" shall not include:

a. An investigational new drug, as defined by 21 CFR 312.3(b), that is being utilized for the purposes of conducting a clinical trial or investigation of such drug or product that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.;

b. Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed by, and being conducted under and pursuant to, 21 CFR 312, et. seq.; or

c. Any drug product being utilized for the purposes of conducting a clinical trial or investigation that is governed or approved by an institutional review board subject to 21 CFR Part 56 or 45 CFR Part 46;

(3) "Out-of-state wholesale drug distributor", a wholesale drug distributor with no physical facilities located in the state;

(4) "Pharmacy distributor", any licensed pharmacy, as defined in section 338.210, engaged in the delivery or distribution of legend drugs to any other licensed pharmacy where such delivery or distribution constitutes at least five percent of the total gross sales of such pharmacy;

(5) "Third-party logistics provider", an entity that provides or coordinates warehousing or other logistics services of a product on behalf of a drug manufacturer, wholesale drug distributor, or dispenser of a legend drug, but does not take

ownership of the product, nor has responsibility to direct the sale or disposition of the product;

(6) "Wholesale drug distributor", anyone engaged in the delivery or distribution of legend drugs from any location and who is involved in the actual, constructive or attempted transfer of a drug or drug-related device in this state, other than to the ultimate consumer. This shall include, but not be limited to, drug wholesalers, repackagers and manufacturers which are engaged in the delivery or distribution of drugs in this state, with facilities located in this state or in any other state or jurisdiction. A wholesale drug distributor shall not include any common carrier or individual hired solely to transport legend drugs. Any locations where drugs are delivered on a consignment basis, as defined by the board, shall be exempt from licensure as a drug distributor, and those standards of practice required of a drug distributor but shall be open for inspection by board of pharmacy representatives as provided for in section 338.360.

(L. 1989 S.B. 39, A.L. 1993 S.B. 27, A.L. 1998 S.B. 940, A.L. 2011 H.B. 412 merged with S.B. 284 merged with S.B. 325, A.L. 2018 H.B. 1719)

338.333. License required, temporary licenses may be granted — out-of-state distributors, reciprocity allowed, when.

1. Except as otherwise provided by the board of pharmacy by rule in the event of an emergency or to alleviate a supply shortage, no person or distribution outlet shall act as a wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider without first obtaining license to do so from the Missouri board of pharmacy and paying the required fee. The board may grant temporary licenses when the wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider first applies for a license to operate within the state. Temporary licenses shall remain valid until such time as the board shall find that the applicant meets or fails to meet the requirements for regular licensure. No license shall be issued or renewed for a wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider to operate unless the same shall be operated in a manner prescribed by law and according to the rules and regulations promulgated by the board of pharmacy with respect thereto. Separate licenses shall be required for each distribution site owned or operated by a wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider, unless such drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider meets the requirements of section 338.335.

2. An agent or employee of any licensed or registered wholesale drug distributor, pharmacy distributor, drug outsourcer, or third-party logistics provider need not seek licensure under this section and may lawfully possess pharmaceutical drugs, if the agent or employee is acting in the usual course of his or her business or employment.

3. The board may permit out-of-state wholesale drug distributors, drug outsourcers, third-party logistics provider, or out-of-state pharmacy distributors to be licensed as required by sections 338.210 to 338.370 on the basis of reciprocity to the extent that the entity both:

(1) Possesses a valid license granted by another state pursuant to legal standards comparable to those which must be met by a wholesale drug distributor, pharmacy distributor, drug outsourcers, or third-party logistics provider of this state as prerequisites for obtaining a license under the laws of this state; and

(2) Distributes into Missouri from a state which would extend reciprocal treatment under its own laws to a wholesale drug distributor, pharmacy distributor, drug outsourcers, or third-party logistics provider of this state.

(L. 1989 S.B. 39 § 338.340, A.L. 2010 H.B. 2226, et al., A.L. 2012 H.B. 1563, A.L. 2018 H.B. 1719)

338.335. Separate licenses required, when — exemptions.

1. Separate licenses shall be required for each distribution site owned or operated by a wholesale drug distributor or pharmacy distributor unless drugs are delivered only on a consignment basis as defined by the board, or the entity meets the requirements of subsection 2 of this section.

2. A wholesale drug distributor distributing drug-related devices in Missouri is not required to obtain a license from the board for out-of-state distribution sites owned by the wholesale drug distributor if:

(1) The wholesale drug distributor has one or more distribution sites located in Missouri, and all such in-state distribution sites receiving shipments of drug-related devices are licensed by the board as a distributor;

(2) The wholesale drug distributor's out-of-state distribution sites shipping to the in-state distribution site are in compliance with their respective state's licensing laws;

(3) The wholesale drug distributor's out-of-state distribution sites that deliver drug-related devices regulated by the board into Missouri for patient use deliver such devices only to the licensed wholesale drug distributor's in-state distribution site.

3. A Missouri wholesale drug distributor receiving shipments of drug-related devices from an out-of-state facility that is not required to be licensed as a distributor pursuant to subsection 2 of this section shall be responsible for all shipments received.

(L. 1998 S.B. 940, A.L. 2010 H.B. 2226, et al.)

338.337. Out-of-state distributors, licenses required, exception.

It shall be unlawful for any out-of-state wholesale drug distributor, out-of-state pharmacy acting as a distributor, drug outsourcers, or third-party logistics provider to do business in this state without first obtaining a license to do so from the board of pharmacy and paying the required fee, except as otherwise provided by section 338.335 and this section. Application for

an out-of-state wholesale drug distributor's, drug outsourcer's, or out-of-state third-party logistics provider's license under this section shall be made on a form furnished by the board. The issuance of a license under sections 338.330 to 338.370 shall not change or affect tax liability imposed by the Missouri department of revenue on any entity. Any out-of-state wholesale drug distributor that is a drug manufacturer and which produces and distributes from a facility which has been inspected and approved by the Food and Drug Administration, maintains current approval by the federal Food and Drug Administration, and has provided a copy of the most recent Food and Drug Administration Establishment Inspection Report to the board, and which is licensed by the state in which the distribution facility is located, or, if located within a foreign jurisdiction, is authorized and in good standing to operate as a drug manufacturer within such jurisdiction, need not be licensed as provided in this section but such out-of-state distributor shall register its business name and address with the board of pharmacy and pay a filing fee in an amount established by the board.

(L. 1989 S.B. 39 § 338.350, A.L. 2009 H.B. 191 merged with S.B. 296, A.L. 2010 H.B. 2226, et al., A.L. 2018 H.B. 1719)

338.340. Sale of drugs, out-of-state distributor, license required.

No person acting as principal or agent for any out-of-state wholesale drug distributor, out-of-state pharmacy distributor, drug outsourcer, or out-of-state third-party logistics provider shall sell or distribute drugs in this state unless the entity has obtained a license pursuant to the provisions of sections 338.330 to 338.370.

(L. 1989 S.B. 39 § 338.360, A.L. 2018 H.B. 1719)

338.343. Records to be maintained and be available for board inspection.

Any licensee licensed under the provisions of sections 338.330 to 338.340 must maintain required records to guarantee security, storage and accountability. These records shall be available for inspection by the board.

(L. 1989 S.B. 39 § 338.370, A.L. 1993 S.B. 27)

338.347. Renewal of license, application.

1. Application blanks for renewal of license shall be mailed to each licensee on or before the first day of the month in which the license expires and, if application for renewal of license with required fee is not made before the first day of the following month, the existing license, or renewal thereof, shall lapse and become null and void upon the last day of that month.
2. The board of pharmacy shall not renew an out-of-state wholesale drug distributor, out-of-state pharmacy distributor, or drug distributor license or registration if the renewal applicant does not hold a current distributor license or its equivalent in the state or jurisdiction in which the distribution facility is located or, if a drug distributor registrant, the entity is not authorized and in good standing to operate as a drug manufacturer with the Food and Drug Administration or within the state or jurisdiction where the facility is located.

(L. 1989 S.B. 39 § 338.380, A.L. 2016 S.B. 865 & 866)

338.350. Board of pharmacy to promulgate rules and regulations — procedure.

The Missouri board of pharmacy may make such rules and regulations, not inconsistent with law, as may be necessary to carry out the purposes and enforce the provisions of sections 338.330 to 338.370. Such rules and regulations shall not be contrary to or more restrictive than any laws or rules pertaining to practices which are regulated by the federal Food and Drug Administration or the federal Drug Enforcement Administration when the laws or rules specifically state what requirements must be met for compliance. As used in this section, rules of the federal government shall not include guidelines or policies that may be enacted by federal agencies. No rule or portion of a rule promulgated under the authority of this chapter shall become effective unless it has been promulgated pursuant to the provisions of section 536.024.

(L. 1989 S.B. 39 § 338.390, A.L. 1993 S.B. 27 merged with S.B. 52, A.L. 1995 S.B. 3)

338.353. Discipline of licensee, grounds — procedure — administrative hearing commission to conduct hearing.

1. The board of pharmacy is hereby authorized and empowered, when complaints, examinations or inspection of a wholesale drug distributor or pharmacy distributor disclose to the board that a wholesale drug distributorship or pharmacy distributorship is not being operated or conducted according to such legal rules and regulations and the laws of Missouri or any other state or the federal government with respect thereto, to cause a complaint to be filed before the administrative hearing commission pursuant to chapter 621 charging the holder of a license to operate a drug distributorship or pharmacy wholesale operation constituting grounds for discipline in accordance with section 338.055.
2. If the board concludes that a wholesale drug distributor or pharmacy distributor has committed an act or is engaging in a course of conduct which constitutes a clear and present danger to the public health and safety in Missouri, the board may file a complaint before the administrative hearing commission requesting an expedited hearing and specifying the activities which give rise to the danger and the nature of the proposed restriction or suspension of the wholesale drug distributor's or pharmacy distributor's license. Within fifteen days after service of the complaint on a wholesale drug distributor or pharmacy distributor, the administrative hearing commission shall conduct a preliminary hearing to determine whether the alleged activities of the

wholesale drug distributor or pharmacy distributor appear to constitute a clear and present danger to the public health and safety which justify that the wholesale drug distributor's or pharmacy distributor's license be immediately restricted or suspended. The burden of proving that a wholesale drug distributor or pharmacy distributor is a clear and present danger to the public health and safety shall be upon the state board of pharmacy. The administrative hearing commission shall issue its decision immediately after the hearing and shall either grant to the board the authority to suspend or restrict the license or dismiss the action.

3. If the administrative hearing commission grants temporary authority to the board to restrict or suspend the wholesale drug distributor's or pharmacy distributor's license, such temporary authority of the board shall become final authority if there is no request by the wholesale drug distributor or pharmacy distributor for a full hearing within thirty days of the preliminary hearing. The administrative hearing commission shall, if requested by the wholesale drug distributor or pharmacy distributor named in the complaint, set a date to hold a full hearing under the provisions of chapter 621 regarding the activities alleged in the initial complaint filed by the board.

4. If the administrative hearing commission dismisses the action filed by the board pursuant to subsection 2 of this section, such dismissal shall not bar the board from initiating a subsequent action on the same grounds.

(L. 1989 S.B. 39 § 338.395, A.L. 2001 H.B. 567)

338.357. Sanction imposed by board, when.

Any probation, restriction, suspension or revocation imposed on a licensee by the board of pharmacy for violations of this chapter shall be determined by the board upon a finding in favor of the board following the hearing held pursuant to section 338.353.

(L. 1989 S.B. 39 § 338.400)

338.360. Inspection of premises allowed, when.

Any person authorized by the board of pharmacy is hereby given the right of entry for inspection during normal business hours upon all open premises purporting or appearing to be used by a wholesale drug distributor or pharmacy distributor in Missouri. Any wholesale drug distributor who provides adequate documentation of the most recent inspection less than two years old by the Food and Drug Administration or other comparable state agency as determined by the board with a satisfactory rating shall be exempt from further inspection by the board of pharmacy. Such an exemption shall not bar the board of pharmacy from initiating an investigation pursuant to a public or governmental complaint received by the board of pharmacy regarding a wholesale drug distributor not licensed by the Food and Drug Administration.

(L. 1989 S.B. 39 § 338.410, A.L. 1993 S.B. 27)

338.365. Injunction may be issued, when, procedure.

1. Upon proper application by the board of pharmacy, a court of competent jurisdiction may grant an injunction, restraining order or other order as may be appropriate to enjoin a person from:

(1) Offering to engage or engaging in the performance of any acts or practices for which a certificate of registration or authority, permit or license is required by this chapter upon a showing that such acts or practices were performed or offered to be performed without a certificate of registration or authority, permit or license; or

(2) Engaging in any practice or business authorized by a certificate of registration or authority, permit or license issued pursuant to this chapter upon a showing that the holder presents a probability of serious danger to the health, safety or welfare of any resident of the state or client or patient.

2. Any such actions shall be commenced either in the county in which such conduct occurred or in the county in which defendant resides.

3. Any action brought pursuant to this section shall be in addition and not in lieu of any penalty provided by law and may be brought concurrently with other actions to enforce this chapter.

(L. 1989 S.B. 39 § 338.415, A.L. 1997 S.B. 141)

338.370. Penalties.

Every person who violates any provision of sections 338.333, 338.337, and 338.340 shall, upon conviction thereof, be adjudged guilty of a class D felony.

(L. 1989 S.B. 39 § 338.420, A.L. 2014 S.B. 491)

WELL-BEING COMMITTEE

338.380. Refusal to issue a certificate, when — impaired license committee authorized, duties, procedures.

1. As used in this section the term "committee" means the well-being committee established under subsection 3 of this section.

2. The board may refuse to issue any certificate of registration or authority, permit or license required under this chapter

for one or any combination of causes stated in subsection 2 of section 338.055, or the board may, as a condition to issuing or renewing any such certificate of registration or authority, permit or license, require a person to submit himself or herself for identification, intervention, treatment, or rehabilitation by the well-being committee as provided in this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621.

3. The board may establish an impaired licensee committee, to be designated as the "Well-being Committee", to promote the early identification, intervention, treatment, and rehabilitation of licensees identified within this chapter, who may be impaired by reasons of illness, substance abuse, or as a result of any physical or mental condition. The board may enter into a contractual agreement for the purpose of creating, supporting and maintaining such a committee. The board may promulgate rules subject to the provisions of this section to effectuate and implement any committee formed under this section. The board may expend appropriated funds necessary to provide for operational expenses of the committee formed under this section. Any member of the committee, as well as any administrator, staff member, consultant, agent or employee of the committee, acting within the scope of his or her duties and without actual malice and all other persons who furnish information to the committee in good faith and without actual malice, shall not be liable for any claim of damages as a result of any statement, decision, opinion, investigation or action taken by the committee or by any individual member of the committee.

4. All information, interviews, reports, statements, memoranda or other documents furnished to or produced by the committee, as well as communications to or from the committee, any findings, conclusions, interventions, treatment, rehabilitation, or other proceedings of the committee which in any way pertain to a licensee who may be, or who actually is, impaired shall be absolutely privileged and confidential.

5. All records and proceedings of the committee which pertain or refer to a licensee who may be, or who actually is, impaired shall be privileged and confidential and shall be used by the committee and its members only in the exercise of the proper function of the committee and shall not be considered public records under chapter 610 and shall only be subject to discovery or introduction as evidence in any civil, criminal, or administrative proceedings except as provided in subsection 6 of this section.

6. The committee may disclose information relative to an impaired licensee only when:

(1) It is essential to disclose the information to further the intervention, treatment, or rehabilitation needs of the impaired licensee and only to those persons or organization with a need to know;

(2) Its release is authorized in writing by the impaired licensee;

(3) The committee is required to make a report to the board; or

(4) The information is subject to a court order.

7. In lieu of the pursuing discipline against a licensee for violating one or more causes stated in subsection 2 of section 338.055, the board may enter into a diversion agreement with a licensee to refer the licensee to the committee under such terms and conditions as are agreed to by the board and licensee. The board shall enter into no more than two diversion agreements with any individual licensee. If the licensee violates a term or condition of a diversion agreement entered into under this section, the board may elect to pursue discipline against the licensee under chapter 621 for the original conduct that resulted in the diversion agreement, or for any subsequent violation of subsection 2 of section 338.055. While the licensee participates in the committee, the time limitations of section 620.154 shall toll under subsection 7 of section 620.154. All records pertaining to diversion agreements are confidential and may only be released under subdivision (7) of subsection 14 of section 620.010.

8. The committee shall report to the board the name of any licensee who fails to enter treatment within forty-eight hours following the provider's determination that the pharmacist needs treatment or any failure by a licensee to comply with the terms of a diversion agreement during inpatient or outpatient treatment or aftercare or report a licensee who resumes the practice of pharmacy before the treatment provider has made a clear determination that the pharmacist is capable of practicing according to acceptable and prevailing standards.

9. The board may disclose information and records to the committee to assist the committee in the identification, intervention, treatment, and rehabilitation of any licensee who may be impaired by reason of illness, substance abuse, or as the result of any physical or mental condition. The committee shall keep all information and records provided by the board confidential to the extent the board is required to treat the information and records as closed to the public under chapter 620.

10. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be invalid and void.

(L. 2007 S.B. 195)

BLOOD CLOTTING THERAPIES

338.400. Standard of care, definitions, rules.

1. As used in this section, the following terms shall mean:

(1) “Ancillary infusion equipment and supplies”, the equipment and supplies required to infuse a blood clotting therapy product into a human vein, including syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold compression packs;

(2) “Assay”, the amount of a particular constituent of a mixture or of the biological or pharmacological potency of a drug;

(3) “Bleeding disorder”, a medical condition characterized by a deficiency or absence of one or more essential blood-clotting components in the human blood, including all forms of hemophilia, von Willebrand’s disease, and other bleeding disorders that result in uncontrollable bleeding or abnormal blood clotting;

(4) “Blood clotting product”, a medicine approved for distribution by the federal Food and Drug Administration that is used for the treatment and prevention of symptoms associated with bleeding disorders, including but not limited to recombinant Factor VII, recombinant-activated Factor VIIa, recombinant Factor VIII, plasma-derived Factor VIII, recombinant Factor IX, plasma-derived Factor IX, von Willebrand factor products, bypass products for patients with inhibitors, prothrombin complex concentrates; and activated prothrombin complex concentrates;

(5) “Home nursing services”, specialized nursing care provided in the home setting to assist a patient in the reconstitution and administration of blood clotting products;

(6) “Home use”, infusion or other use of a blood clotting product in a place other than a hemophilia treatment center, hospital, emergency room, physician’s office, outpatient facility, or clinic;

(7) “Pharmacy”, an entity engaged in practice of pharmacy as defined in section 338.010 that provides patients with blood clotting products and ancillary infusion equipment and supplies.

2. The Missouri state board of pharmacy shall promulgate rules governing the standard of care for pharmacies dispensing blood clotting therapies. Such rules shall include, when feasible, the standards established by the medical advisory committees of the patient groups representing the hemophilia and von Willebrand diseases, including but not limited to Recommendation 188 of the National Hemophilia Foundation’s Medical and Scientific Advisory Council. Such rules shall include safeguards to ensure the pharmacy:

(1) Has the ability to obtain and fill a physician prescription as written of all brands of blood clotting products approved by the federal Food and Drug Administration in multiple assay ranges of low, medium, and high, as applicable, and vial sizes, including products manufactured from human plasma and those manufactured from recombinant technology techniques, provided manufacturer supply exists and payer authorization is obtained;

(2) Provides for the shipment of prescribed blood clotting products to the patient within two business days or less for established patients and three business days or less for new patients in nonemergency situations;

(3) Provides established patients with access to blood clotting products within twelve hours of notification by the physician of the patient’s emergent need for blood clotting products;

(4) Provides all ancillary infusion equipment and supplies necessary for established patients for administration of blood clotting products;

(5) Has a pharmacist available twenty-four hours a day, seven days a week, every day of the year, either onsite or on call, to fill prescriptions for blood clotting products;

(6) Provides patients who have received blood clotting products with a designated contact telephone number for reporting problems with a delivery or product;

(7) Provides patients with notification of recalls and withdrawals of blood clotting products and ancillary infusion equipment within twenty-four hours of receipt of the notification; and

(8) Provides containers for the disposal of hazardous waste, and provides* patients with instructions on the proper collection, removal, and disposal of hazardous waste under state and federal law.

3. Notwithstanding the provisions of subsection 2 of this section, pharmacies and pharmacists shall exercise that degree of skill and learning ordinarily exercised by members of their profession in the dispensing and distributing of blood clotting products.

(L. 2011 H.B. 552)

**Word “provide” appears in original rolls.*

Pharmacy Tax

338.500. Gross retail prescriptions, tax imposed, definitions.

1. In addition to all other fees and taxes required or paid, a tax is hereby imposed upon licensed retail pharmacies for the privilege of providing outpatient prescription drugs in this state. The tax is imposed upon the Missouri gross retail prescription receipts earned from filling outpatient retail prescriptions.

2. For purposes of sections 338.500 to 338.550:

(1) “Gross retail prescription receipts” shall mean all amounts received by a licensed pharmacy for its own account from the sale of outpatient prescription drugs in the state of Missouri but shall not include those sales shipped out of the state of Missouri and shall include the receipts from cost sharing, dispensing fees, and retail prescription drug sales;

(2) “Licensed pharmacy” shall have the same meaning as such term is defined in section 338.210;

(3) “Retail” means a sale for use or consumption and not for resale.

(L. 2002 S.B. 1248)

338.505. Formula for tax liability, rulemaking authority, appeals procedure.

1. Each licensed retail pharmacy's tax shall be based on a formula set forth in rules promulgated by the department of social services. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2002, shall be invalid and void.

2. The director of the department of social services or the director's designee may prescribe the form and contents of any forms or other documents required by sections 338.500 to 338.550.

3. Notwithstanding any other provision of law to the contrary, appeals regarding the promulgation of rules pursuant to this section shall be made to the circuit court of Cole County. The circuit court of Cole County shall hear the matter as the court of original jurisdiction.

(L. 2002 S.B. 1248)

338.510. Records to be maintained, form — report of gross receipts, information — confidentiality of information.

1. Each licensed retail pharmacy shall keep such records as may be necessary to determine gross retail prescription receipts.

2. The director of revenue may prescribe the form and contents of any forms or other documents required by this section.

3. Each licensed retail pharmacy shall report the gross retail prescription receipts to the department of revenue.

4. The department of revenue shall provide the department of social services with the information that is necessary to implement the provisions of sections 338.500 to 338.550.

5. The information obtained by the department of social services from the department of revenue shall be confidential and any employee of the department of social services who unlawfully discloses any such information for any other purpose, except as authorized by law, shall be subject to the penalties specified in section 32.057.

(L. 2002 S.B. 1248)

338.515. Effective date of tax.

The tax imposed by sections 338.500 to 338.550 shall become effective July 1, 2003, or the effective date of sections 338.500 to 338.550, whichever is later.

(L. 2002 S.B. 1248, A.L. 2003 H.B. 286)

338.520. Calculation of tax liability — notification to pharmacies — quarterly adjustment authorized.

1. The determination of the amount of tax due shall be the monthly gross retail prescription receipts reported to the department of revenue multiplied by the tax rate established by rule by the department of social services. Such tax rate may be a graduated rate based on gross retail prescription receipts and shall not exceed a rate of six percent per annum of gross retail prescription receipts; provided, that such rate shall not exceed one-tenth of one percent per annum in the case of licensed pharmacies of which eighty percent or more of such gross receipts are attributable to prescription drugs that are delivered directly to the patient via common carrier, by mail, or a courier service.

2. The department of social services shall notify each licensed retail pharmacy of the amount of tax due. Such amount may be paid in increments over the balance of the assessment period.

3. The department of social services may adjust the tax rate quarterly on a prospective basis. The department of social services may adjust more frequently for individual providers if there is a substantial and statistically significant change in their pharmacy sales characteristics. The department of social services may define such adjustment criteria by rule.

(L. 2002 S.B. 1248, A.L. 2003 H.B. 286 merged with H.B. 600)

338.530. Offset against Medicaid payments due by pharmacy permitted, when.

The director of the department of social services may offset the tax owed by a pharmacy against any Missouri Medicaid payment due such pharmacy, if the pharmacy requests such an offset. The amounts to be offset shall result, so far as practicable, in withholding from the pharmacy an amount substantially equal to the assessment due from the pharmacy. The office of administration and the state treasurer may make any fund transfers necessary to execute the offset.

(L. 2002 S.B. 1248)

338.535. Remittance to department — pharmacy reimbursement allowance fund created.

1. The pharmacy tax owed or, if an offset has been made, the balance after such offset, if any, shall be remitted by the pharmacy or the pharmacy's designee to the department of social services. The remittance shall be made payable to the director of the department of revenue and shall be deposited in the state treasury to the credit of the "Pharmacy Reimbursement Allowance Fund" which is hereby created to provide payments for services related to the Medicaid pharmacy program.

All investment earnings of the fund shall be credited to the fund.

2. An offset authorized by section 338.530 or a payment to the pharmacy reimbursement allowance fund shall be accepted as payment of the obligation set forth in section 338.500.

3. The state treasurer shall maintain records showing the amount of money in the pharmacy reimbursement allowance fund at any time and the amount of investment earnings on such amount.

4. Notwithstanding the provisions of section 33.080 to the contrary, any unexpended balance in the pharmacy reimbursement allowance fund at the end of the biennium shall not revert to the credit of the general revenue fund.

(L. 2002 S.B. 1248, A.L. 2009 H.B. 395 merged with H.B. 740)

338.540. Notice requirements — unpaid or delinquent taxes, procedure for collection — failure to pay taxes, effect of.

1. The department of social services shall notify each pharmacy with a tax due of more than ninety days of the amount of such balance. If any pharmacy fails to pay its pharmacy tax within thirty days of such notice, the pharmacy tax shall be delinquent.

2. If any tax imposed pursuant to sections 338.500 to 338.550 is unpaid and delinquent, the department of social services may proceed to enforce the state's lien against the property of the pharmacy and compel the payment of such assessment in the circuit court having jurisdiction in the county where the pharmacy is located. In addition, the department of social services may cancel or refuse to issue, extend, or reinstate a Medicaid provider agreement to any pharmacy that fails to pay the tax imposed by section 338.500.

3. Failure to pay the tax imposed by section 338.500 shall be grounds for denial, suspension, or revocation of a license granted pursuant to this chapter. The department of social services may request the board of pharmacy to deny, suspend, or revoke the license of any pharmacy that fails to pay such tax.

(L. 2002 S.B. 1248)

338.550. Expiration date of tax, when.

1. The pharmacy tax required by sections 338.500 to 338.550 shall expire ninety days after any one or more of the following conditions are met:

(1) The aggregate dispensing fee as appropriated by the general assembly paid to pharmacists per prescription is less than the fiscal year 2003 dispensing fees reimbursement amount; or

(2) The formula used to calculate the reimbursement as appropriated by the general assembly for products dispensed by pharmacies is changed resulting in lower reimbursement to the pharmacist in the aggregate than provided in fiscal year 2003; or

(3) September 30, 2024.

The director of the department of social services shall notify the revisor of statutes of the expiration date as provided in this subsection. The provisions of sections 338.500 to 338.550 shall not apply to pharmacies domiciled or headquartered outside this state which are engaged in prescription drug sales that are delivered directly to patients within this state via common carrier, mail or a carrier service.

2. Sections 338.500 to 338.550 shall expire on September 30, 2024.

(L. 2002 S.B. 1248, A.L. 2003 H.B. 286 merged with H.B. 600, A.L. 2005 S.B. 189, A.L. 2006 S.B. 822, A.L. 2007 S.B. 4, A.L. 2009 H.B. 395 merged with H.B. 740, A.L. 2011 S.B. 62, A.L. 2015 S.B. 210, A.L. 2016 H.B. 1534, A.L. 2018 S.B. 775, A.L. 2019 S.B. 29, A.L. 2020 H.B. 2456, A.L. 2021 1st Ex. Sess. S.B. 1)

PHARMACY AUDITS

338.600. Criteria for audit — appeals process to be established — report to be provided — applicability exceptions.

1. Notwithstanding any other provision of law to the contrary, when an audit of the records of a pharmacy licensed in this state is conducted by a managed care company, insurance company, third-party payor, or any entity that represents such companies or groups, such audit shall be conducted in accordance with the following:

(1) The entity conducting the initial on-site audit shall provide the pharmacy with notice at least one week prior to conducting the initial on-site audit for each audit cycle;

(2) Any audit which involves clinical judgment shall be conducted by or in consultation with a licensed pharmacist;

(3) Any clerical error, record-keeping error, typographical error, or scrivener's error regarding a required document or record shall not constitute fraud or grounds for recoupment, so long as the prescription was otherwise legally dispensed and the claim was otherwise materially correct; except that, such claims may be otherwise subject to recoupment of overpayments or payment of any discovered underpayment. No claim arising under this subdivision shall be subject to criminal penalties without proof of intent to commit fraud;

(4) A pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts involving drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug. Electronically stored images of prescriptions,

electronically created annotations and other related supporting documentation shall be considered valid prescription records. Hard copy and electronic signature logs that indicate the delivery of pharmacy services shall be considered valid proof of receipt of such services by a program enrollee;

(5) A finding of an overpayment or underpayment may be a projection based on the number of patients served and having a similar diagnosis or on the number of similar orders or refills for similar drugs; except that, recoupment of claims shall be based on the actual overpayment or underpayment unless the projection for overpayment or underpayment is part of a settlement as agreed to by the pharmacy;

(6) Each pharmacy shall be audited under the same standards and parameters as other pharmacies audited by the entity;

(7) A pharmacy shall be allowed at least thirty days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during an audit;

(8) The period covered by the audit shall not exceed a two-year period beginning two years prior to the initial date of the on-site portion of the audit unless otherwise provided by contractual agreement or if there has been a previous finding of fraud or as otherwise provided by state or federal law;

(9) An audit shall not be initiated or scheduled during the first three business days of any month due to the high volume of prescriptions filled during such time unless otherwise consented to by the pharmacy;

(10) The preliminary audit report shall be delivered to the pharmacy within one hundred twenty days after conclusion of the audit, with reasonable extensions permitted. A final audit report shall be delivered to the pharmacy within six months of receipt by the pharmacy of the preliminary audit report or final appeal, as provided for in subsection 3 of this section, whichever is later;

(11) Notwithstanding any other provision in this subsection, the entity conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits, except as otherwise authorized under subdivision (5) of this subsection.

2. Recoupments of any disputed moneys shall only occur after final internal disposition of the audit, including the appeals process set forth in subsection 3 of this section. Should the identified discrepancy for an individual audit exceed twenty-five thousand dollars, future payments to the pharmacy in excess of twenty-five thousand dollars may be withheld pending finalization of the audit.

3. Each entity conducting an audit shall establish an appeals process, lasting no longer than six months, under which a licensed pharmacy may appeal an unfavorable preliminary audit report to the entity. If, following such appeal, the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or such portion without the necessity of any further proceedings.

4. Each entity conducting an audit shall provide a copy of the final audit report, after completion of any appeal process, to the plan sponsor.

5. This section shall not apply to any investigative audit that involves probable fraud, willful misrepresentation, or abuse.

6. This section shall not apply to any audit conducted as part of any inspection or investigation conducted by any governmental entity or law enforcement agency.

(L. 2008 S.B. 1068)

PHARMACY REBATES FUND

338.650. Fund established, use of moneys.

There is hereby established in the state treasury the "Pharmacy Rebates Fund". Any revenues received by the state, either directly or indirectly, from pharmaceutical manufacturer rebates as required by federal law, except where federal law requires rebates to be accounted for otherwise, or state supplemental rebates as defined in state plan amendments shall be deposited into the pharmacy rebates fund and shall be used only in the MO HealthNet pharmacy program or its successor programs authorized under Title XIX, Public Law 89-97, 1965 amendments to the federal Social Security Act, 42 U.S.C. Section 301, et seq.

(L. 2008 S.B. 1068)

NICOTINE REPLACEMENT THERAPY PRODUCTS

338.665. Nicotine replacement therapy product, defined — prescribing and dispensing, rulemaking authority.

1. For the purposes of this chapter, "nicotine replacement therapy product" means any drug or product, regardless of whether it is available over-the-counter, that delivers small doses of nicotine to a person and that is approved by the federal Food and Drug Administration for the sole purpose of aiding in tobacco cessation or smoking cessation.

2. The board of pharmacy and the board of healing arts shall jointly promulgate rules governing a pharmacist's authority to prescribe and dispense nicotine replacement therapy products. Neither board shall separately promulgate rules governing a pharmacist's authority to prescribe and dispense nicotine replacement therapy products under this subsection.

3. Nothing in this section shall be construed to require third-party payment for services described in this section.

4. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2019, shall be invalid and void.

(L. 2019 S.B. 514)

RX CARES FOR MISSOURI PROGRAM

338.700. Definitions.

As used in sections 338.700 to 338.710, the following terms shall mean:

(1) "Board", the Missouri board of pharmacy;

(2) "Department", the Missouri department of health and senior services;

(3) "Program", the RX cares for Missouri program.

(L. 2017 S.B. 139)

338.710. Program created, goal — authority of board — evaluation report — expiration date.

1. There is hereby created in the Missouri board of pharmacy the "RX Cares for Missouri Program". The goal of the program shall be to promote medication safety and to prevent prescription drug abuse, misuse, and diversion in Missouri.

2. The board, in consultation with the department, shall be authorized to expend, allocate, or award funds appropriated to the board to private or public entities to develop or provide programs or education to promote medication safety or to suppress or prevent prescription drug abuse, misuse, and diversion in the state of Missouri. In no case shall the authorization include, nor the funds be expended for, any state prescription drug monitoring program including, but not limited to, such as are defined in 38 CFR 1.515. Funds disbursed to a state agency under this section may enhance, but shall not supplant, funds otherwise appropriated to such state agency.

3. The board shall be the administrative agency responsible for implementing the program in consultation with the department. The board and the department may enter into interagency agreements between themselves to allow the department to assist in the management or operation of the program. The board may award funds directly to the department to implement, manage, develop, or provide programs or education pursuant to the program.

*4. After a full year of program operation, the board shall prepare and submit an evaluation report to the governor and the general assembly describing the operation of the program and the funds allocated. Unless otherwise authorized by the general assembly, the program shall expire on August 28, 2026.

(L. 2017 S.B. 139, A.L. 2021 H.B. 476 merged with S.B. 63)
**Program expires 8-28-26*

HIV POSTEXPOSURE PROPHYLAXIS

338.730. HIV postexposure prophylaxis, dispensing of, requirements — definitions — rulemaking authority.

1. Notwithstanding any other law to the contrary, a pharmacist may dispense HIV postexposure prophylaxis in accordance with this section. Such prophylaxis shall be dispensed only if the pharmacist follows a written protocol authorized by a licensed physician.

2. For purposes of this section, "postexposure prophylaxis" shall mean any drug approved by the Food and Drug Administration that meets the same clinical eligibility recommendations provided in CDC guidelines.

3. For purposes of this section, "CDC guidelines" shall mean the current HIV guidelines published by the federal Centers for Disease Control and Prevention.

4. The state board of registration for the healing arts and the state board of pharmacy shall jointly promulgate rules and regulations for the administration of this section. Neither board shall separately promulgate rules governing a pharmacist's authority to dispense HIV postexposure prophylaxis under this section.

5. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2021, shall be invalid and void.

(L. 2021 H.B. 273 merged with H.B. 476)

20 CSR Chapter 2220 (Bd. of Pharmacy Rules)

RULE INDEX

CHAPTER 1: ORGANIZATION AND DESCRIPTION OF BOARD

CHAPTER 2: GENERAL RULES

CHAPTER 7: LICENSING

CHAPTER 8: THIRD-PARTY LOGISTIC PROVIDERS AND DRUG OUTSOURCER FACILITIES

20 CSR 2220-1

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE

Division 2220—State Board of Pharmacy

Chapter 1—Organization and Description of Board

20 CSR 2220-1.010 General Organization

PURPOSE: The purpose of this regulation is to comply with section 536.023(3), RSMo (1986) which requires each agency to adopt as a regulation, a description of its operation and the methods and procedures where the public may obtain information or make submissions or requests.

(1) The State Board of Pharmacy is a unit of the Division of Professional Registration of the Department of Commerce and Insurance.

(2) The board was created by House Bill No. 87 of the General Assembly of 1909.

(3) The State Board of Pharmacy shall consist of seven (7) persons not connected with any school of pharmacy. Annually the board shall organize by the election of a president and vice president each of whom serves for one (1) year. Six (6) members shall be licensed as pharmacists and actively engaged in the practice of pharmacy within this state and at least one (1) of these shall be a person who provides, on a full-time basis, pharmaceutical services to a hospital, skilled nursing facility or an intermediate care facility. The other member shall be a voting public member. All members shall be appointed by the governor, with the approval of the senate and shall hold their offices for five (5) years from the date of their appointments and until their successors shall have been appointed and qualified.

(4) The board is directed by sections 338.140, 338.280 and 338.350, RSMo to adopt rules for the application and enforcement of Chapter 338, RSMo which also requires compliance of Chapter 195, RSMo.

(5) The board has superintending control over the practice of pharmacy and drug distributors and its primary duties consist of—

(A) Examining and licensing of applicants;

(B) Assisting in the accrediting of pharmacy colleges and approval of their programs;

(C) Renewing annually the license of qualified pharmacists, pharmacies, intern pharmacists and drug distributors;

(D) Suspending, revoking, placing on probation or censure of licenses of any pharmacist, pharmacy, intern pharmacist or drug distributors found guilty of violating the provisions set forth in Chapter 338, RSMo;

(E) Inspecting pharmacies and drug distributors;

(F) Inspecting and certification of pharmacies as intern-training pharmacies;

(G) Interacting and participating with various state and national organizations in order to facilitate the exchange of information, policies and procedures and techniques that can assist the board in fulfilling its mission; and

(H) Interacting with other state and federal agencies as concerns the enforcement of state and federal drug laws.

(6) "Open premises" as used in Chapter 338, RSMo means all premises accessible to employees in the regular course of any business which engages in practices regulated by this chapter, including, but not limited to, locked or otherwise secured storage areas that are used for the purpose of storing drugs, poisons, chemicals, or equipment used in any practice regulated by this chapter, and/or storage areas that are used for the purpose of storing records related to any practice regulated by this chapter.

(7) The public may obtain information from the board, or make submissions or requests to the board, by writing the executive director of the board. The information request shall be reviewed for appropriate action.

AUTHORITY: sections 338.110, 338.140 and 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-1.010. Original rule filed Dec. 31, 1975, effective Jan. 10, 1976. Amended: Filed April 14, 1982, effective July 11, 1982. Amended: Filed Jan. 3, 1990, effective May 11, 1990. Amended: Filed Aug. 25, 1996, effective April 30, 1996. Amended: Filed May 13, 2005, effective Oct. 30, 2005. Moved to 20 CSR 2220-1.010, effective Aug. 28, 2006. Non-substantive change filed July 30, 2019, published Sept. 30, 2019.*

**Original authority 338.110, RSMo 1939, amended 1949, 1981, 1999; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-1.020 Board Compensation

PURPOSE: This rule fixes the compensation for the members of the State Board of Pharmacy in compliance with the mandates of section 338.130, RSMo (1986).

(1) Each member of the State Board of Pharmacy shall receive as compensation the sum of fifty dollars ($50) for each day that member devotes to the affairs of the board.

(2) In addition to the compensation fixed in this rule, each member is entitled to reimbursement of his/her expenses necessarily incurred in the discharge of his/her official duties.

(3) No request for the compensation provided in this rule shall be processed for payment unless sufficient funds are available for that purpose within the appropriation for this board.

AUTHORITY: sections 338.130 and 338.140, RSMo 1986. This rule originally filed as 4 CSR 220-1.020. Emergency rule filed Sept. 11, 1981, effective Sept. 28, 1981, expired Jan. 13, 1982. Original rule filed Sept. 11, 1981, effective Jan. 14, 1982. Moved to 20 CSR 2220-1.020, effective Aug. 28, 2006.*

**Original authority: 338.130, RSMo 1939, amended 1949, 1961, 1969, 1981, 1997; 338.140, RSMo 1939, amended 1981, 1989, 1997.*

20 CSR 2220-2

TITLE 20 — DEPARTMENT OF COMMERCE AND INSURANCE
Division 2220 — State Board of Pharmacy
Chapter 2 — General Rules

20 CSR 2220-2.005 Definitions

PURPOSE: This rule defines the term "drug" as utilized in Chapter 338, RSMo, and the rules of the board.

(1) "Drug," "prescription drug," or "legend drug" means any drug or biological product —

(A) Subject to section 503(b) of the Federal Food, Drug and Cosmetic Act, including finished dosage forms and active ingredients subject to section 503(b);

(B) Required by federal law to be labeled with one (1) of the following statements, prior to being dispensed or delivered:

1. "Caution: Federal law prohibits dispensing without prescription";

2. "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

3. "Rx Only"; and

(C) Required by any applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use by practitioners only.

(2) For purposes of sections 338.300 to 338.370, RSMo, the term "drug," "prescription drug," or "legend drug" shall not include:

(A) An investigational new drug or biological product, as defined by 21 CFR 312.3(b), that is being utilized for the purposes of conducting a clinical trial/investigation of that drug or product if such clinical trial/investigation is governed by, and being conducted pursuant to, 21 CFR 312, et seq.;

(B) A legend drug or biological product being utilized for the purposes of a clinical trial/investigation that is governed by, and being conducted pursuant to, 21 CFR 312, et seq.; or

(C) A legend drug or biological product being utilized for the purposes of a clinical trial/investigation that is governed or approved by an institutional review board subject to 21 CFR 56 or 45 CFR Part 46.

AUTHORITY: section 338.010, RSMo Supp. 2010 and sections 338.140, 338.280, and 338.350, RSMo 2000. Emergency rule filed Sept. 3, 2010, effective Sept. 13, 2010, expired March 11, 2011. Original rule filed March 7, 2011, effective Aug. 30, 2011.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.280, RSMo 1951, amended 1971, 1981; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-2.010 Pharmacy Standards of Operation

PURPOSE: This rule defines terms used in the regulations of the State Board of Pharmacy and outlines the conditions necessary for the operation of a pharmacy.

(1) Pharmacies must be safely operated at all times, in compliance with applicable state and federal law. Except as otherwise provided by law, pharmacies must also comply with the following:

(A) Pharmacies shall not introduce or enforce any policies, procedures, systems, or practices that jeopardize, inhibit, or threaten patient safety or the safe provision of pharmacy services. A licensed pharmacist must be physically present within the confines of the dispensing area of a licensed pharmacy whenever any person other than a licensed pharmacist compounds, prepares, dispenses, or any way provides a drug, medicine, or poison pursuant to a lawful prescription or medication order. The pharmacist must be able to render immediate assistance and able to identify and correct any errors before the drug, medicine, or poison is dispensed or sold. A sign advising the public that no pharmacist is on duty must be manually or electronically posted when no pharmacist is on duty at the pharmacy. The signs must be prominently displayed on all entrance doors and the prescription counter of the pharmacy. Sign lettering must be at least two inches (2") in height;

(B) Except as otherwise provided by law, a pharmacist shall personally inspect and verify the accuracy of the final contents of any prescription or medication order and the affixed label prior to dispensing;

(C) Adequate staffing and resources must be provided to allow licensees/registrants to safely and accurately provide pharmacy services. Pharmacies must be equipped with properly functioning pharmaceutical equipment for the pharmacy services performed as recognized by the latest edition of the *United States Pharmacopoeia* (USP) or *Remington's Pharmaceutical Sciences*;

(D) References/resources must be physically maintained or immediately accessible in electronic form at the pharmacy that include the following:

1. A current print or electronic edition of statutes and rules governing the pharmacy's practice, including, but not limited to, Chapters 338 and 195, RSMo, 20 CSR 2220 and, if applicable, 19 CSR 30 governing controlled substances;

2. Generally recognized reference(s) or other peer-reviewed resource(s) that include the following items/topics:

A. All drugs approved by the United States Federal Drug Administration (FDA) as appropriate to the practice site;

B. Pharmacology of drugs;

C. Dosages and clinical effects of drugs; and

D. Patient information and counseling;

(E) All Missouri and federal pharmacy licenses, permits, or registrations must be current and accurate, including the pharmacy's name, permit classification(s), and address;

(F) Individuals practicing or assisting in the practice of pharmacy must be appropriately licensed or registered with the board and appropriately trained and competent to perform assigned duties. Any person other than a pharmacist or permit holder who has independent access to legend drug stock on a routine basis in a pharmacy must be registered or licensed with the board as a pharmacy technician or intern pharmacist. Except as otherwise authorized by law, non-resident pharmacists providing pharmacy services for patients or pharmacies located in Missouri must hold a Missouri pharmacist license or must be working for a Missouri licensed pharmacy;

(G) Pharmacy facilities and equipment must be maintained in a clean and sanitary condition at all times and trash must be disposed of in a timely manner.

1. Appropriate sewage disposal and a hot and cold water supply within the pharmacy must be available. The required water supply may not be located in a bathroom.

2. Waste and hazardous materials must be handled and disposed of in compliance with applicable state and federal law.

3. The pharmacy must be free from insects, vermin, and animals of any kind. Animals are not allowed in pharmacies, except for service animals as defined by the Americans with

Disabilities Act (ADA);

(H) Adequate security and locking mechanisms must be maintained to prevent unauthorized access to the pharmacy and to ensure the safety and integrity of drugs and confidential records. Pharmacy traffic must be restricted to authorized persons so that proper control over drugs and confidential records can be maintained at all times. Pharmacies dispensing or stocking controlled substances must comply with all federal and state controlled substance security requirements;

(I) Medication and drug-related devices must be properly and accurately prepared, packaged, dispensed, distributed, and labeled under clean, and when required, aseptic conditions. Staff must wear disposable gloves when physically touching individual dosage units. Pharmacies shall not fill or refill any prescription or medication order after one (1) year from the date issued by the prescriber;

(J) Offsite storage. Pharmacies may maintain storage sites or warehouse facilities for the storage of pharmaceuticals or required/confidential pharmacy records at a separate address or premises from the main pharmacy, provided the storage facility is registered with the board. To register, the pharmacy must submit the following to the board in writing: the storage facility's address, hours of operation (if applicable), and the pharmacy permit numbers of the pharmacies that utilize the facility. No registration fee is required.

1. Adequate security and storage conditions must be maintained at these facilities to guarantee the security and integrity of records, medication, and drug-related devices. At a minimum, storage facilities must maintain a functioning alarm system. Any breach in security must be documented and reported to the board electronically or in writing within fifteen (15) days of the breach.

2. Medication stored at an offsite storage facility pursuant to this subsection may only be used by a pharmacy for the sole purpose of distributing drugs solely within its own pharmacy operations. A drug distributor license is required if an offsite storage facility is used to store/distribute medication for multiple pharmacies, regardless of pharmacy ownership.

3. No record less than two (2) years old may be stored offsite. Patient records stored at an offsite facility must be retrievable within two (2) business days of a request from the board or its authorized designee.

4. Storage and warehouse locations will be considered facilities of a pharmacy pursuant to section 338.240, RSMo, and will be subject to inspection by the board pursuant to section 338.150, RSMo;

(K) If the pharmacy is located in a facility that is accessible to the public and the pharmacy's hours of operation are different from those of the remainder of the facility, ceilings and walls must be constructed of a substantial material so that the pharmacy permit area is separate and distinct from the remainder of the facility. Drop down ceilings or other openings that would allow unauthorized access into the pharmacy are not allowed;

(L) Licensee/Registrant Identification and Signage.

1. All board licensees and registrants must wear an identification badge or similar identifying article that identifies their name and title when practicing or assisting in the practice of pharmacy (e.g., pharmacist, pharmacy technician, intern pharmacist).

2. The licenses/registrations for all pharmacists, technicians, and intern pharmacists regularly working in the pharmacy must be maintained in a central location on the premises of the pharmacy. Individual licenses/registrations must have a photo attached that is not smaller than two by two inches (2" x 2"). The required licenses/registrations must be immediately retrievable during an inspection or available to the public if requested. Licensees or registrants regularly working for more than one (1) pharmacy, temporarily working as a relief pharmacist outside of their regular pharmacy work location, or practicing pharmacy at a non-pharmacy location must have proper identification of their pharmacy license in their possession while practicing or assisting in the practice pharmacy (e.g., wallet card, current online verification).

3. A sign must be physically or electronically posted at the pharmacy indicating that the pharmacy is licensed and regulated by the Missouri Board of Pharmacy along with the board's current address, telephone number, and primary email address. The board will provide the required sign at no cost. Alternatively, licensees may post an electronic copy of the required sign, provided the size and type of the electronic sign and lettering equals or exceeds the board issued sign and the electronic sign is constantly visible by the public during the pharmacy's normal business hours. The required sign must be prominently posted in close proximity to the pharmacy in a manner and location that is easily viewable and readable by the public;

(M) All board licensed pharmacies must be under the supervision of a pharmacist-in-charge designated with the board who holds a current and active Missouri pharmacist license. The pharmacist-in-charge must be actively engaged in pharmacy activities at the pharmacy and must be physically present at the pharmacy for a sufficient amount of time as needed to effectively supervise pharmacy activities and ensure pharmacy compliance. For pharmacies located outside of Missouri, the designated pharmacist-in-charge must hold a current and active pharmacist license in the state where the pharmacy is located.

1. In the event the pharmacist-in-charge designated with the board changes, the pharmacy may not continue operations until a new pharmacist-in-charge is named, except as otherwise authorized by this rule. A change of pharmacist-in-charge application must be submitted to the board with the applicable fee within fifteen (15) calendar days after a new pharmacist-in-charge is designated. A controlled substance inventory must be taken at or immediately prior to a pharmacist-in-charge change as required by 20 CSR 2220-2.090.

2. If a new pharmacist-in-charge cannot be immediately designated after a pharmacist-in-charge change despite reasonable diligence, the pharmacy may appoint an interim supervising pharmacist for a period not to exceed thirty (30) days. The interim supervising pharmacist must meet the requirements of this rule and file a statement on a form approved by the board agreeing to be responsible for pharmacy compliance while serving as the interim supervising pharmacist. A documented controlled substance inventory must be taken when the interim supervising pharmacist is designated. Written notification of the interim supervising pharmacist designation must be immediately provided to the board at the board's electronic mail address or via facsimile on a form approved by the board along with the required interim supervising pharmacist form; and

(N) Licensees and registrants must maintain a current mailing address on file with the board. Licensees/registrants must notify the board electronically or in writing of any change in their mailing or employment address, within fifteen (15) days following the change;

(O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter

338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.

(2) Drug Storage. Drugs must be properly stored and maintained in a thermostatically controlled area within temperature and humidity requirements as provided in the Food and Drug Administration approved drug product labeling or the *United States Pharmacopeia* (USP).

(A) Temperatures in drug storage areas must be recorded and reviewed at least once each day the pharmacy is in operation. Alternatively, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings that alerts a pharmacist when temperatures are outside of the required range and provides the amount of variance.

(B) No outdated, misbranded, or adulterated drugs or devices may be dispensed, distributed, or maintained within the pharmacy's active inventory, including prescription and related nonprescription items. Outdated, misbranded, or adulterated medication and medication for personal employee use must be quarantined in an area that is clearly identified and physically separate from medication maintained for dispensing, distribution, or other pharmacy use. Drugs for the personal use of pharmacy staff or personnel must be labeled in accordance with section 338.059, RSMo, or as otherwise required by law.

(C) Food and beverage items that are not in their original, sealed manufacturer packaging must be stored separately from medication and medication-related devices. Open food or beverages used in compounding or intended for patient use with medication may be stored in the same area as drugs and drug-related devices, provided the items must be separated from other inventory and sanitary conditions are maintained at all times.

(D) Appropriate lighting, ventilation, and humidity must be maintained in areas where drugs are stored and dispensed. Medication may not be stored on the floor.

(E) Drug samples shall not be maintained in or dispensed by pharmacies, except as otherwise authorized by state and federal law, including, but not limited to, 21 U.S.C. section 353 and the federal Prescription Drug Marketing Act of 1987.

(3) Record Keeping. Pharmacy records must be accurately maintained in compliance with applicable state and federal law. Records required by Chapters 195 and 338, RSMo, or divisions 20 CSR 2220 and 19 CSR 30 shall be available for inspection, photographing, or duplication by a board representative.

(A) Pharmacies must maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of legend drugs. Each pharmacy shall designate either a primary manual or electronic record keeping system which will be used to record the dispensing of all prescriptions and medication orders. Poison sales may be recorded in a separate manual log. Except as otherwise authorized or required by law, at least three (3) separate files of prescriptions/medication orders must be maintained:

1. A separate file for Schedule I and II controlled substances;
2. A separate file for Schedules III, IV, and V controlled substances; and
3. A separate file(s) for all other prescriptions/medication orders.

(B) Distribution records. Unless otherwise authorized by law or the board, pharmacies shall maintain inventories and records of all legend drugs received and distributed that include:

1. The date of the transaction/distribution;
2. Product name, strength, and quantity;
3. The names of the parties;
4. The sender's address or, for drugs distributed by the pharmacy, the receiver's address; and
5. Any other information required by state or federal law.

(C) Unless otherwise provided by law, records required by Chapter 338 or 20 CSR 2220 that do not have a specified retention time must be kept for two (2) years and readily retrievable at the request of the board or the board's authorized designee. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from the board or the board's authorized designee, or by making a computer terminal available to the inspector for immediate use to review the records requested. Records not maintained at a pharmacy must be produced within three (3) business days of a board request.

(4) Mandatory Reporting. Licensees, registrants, and permit holders must notify the board of any adverse action by another licensing state, jurisdiction, or government agency against the licensee/registrants/permit holder as required by section 338.075, RSMo, within fifteen (15) days of such action. Additionally, pharmacies must notify the board within fifteen (15) days of any final disciplinary action taken against a pharmacist, intern pharmacist, or pharmacy technician for conduct that might have led to disciplinary action under section 338.055, RSMo, or resignation of a licensee/registrant in lieu of such final disciplinary action. The notification must be provided in writing or electronically and include:

(A) The pharmacy's name and permit number;

(B) Name and contact information for person making the notification;

(C) The licensee's or registrant's name and license/registration number;

(D) Date of action; and

(E) Reason for action.

(5) A home health or hospice agency licensed or certified according to Chapter 197, RSMo, or any licensed nurses of such agency, may possess drugs in the usual course of business of such agency without being licensed as a pharmacist or a pharmacy.

(A) The following legend drugs/devices may be possessed by a home health or hospice agency identified in this section without a pharmacy license or permit:

1. Injectable dosage forms of sodium chloride and water;
2. Irrigation dosage forms of sodium chloride and water that carry a federal prescription only restriction;
3. Injectable dosage forms of heparin and alteplase in concentrations that are indicated for maintenance of venous access devices;
4. Injectable dosage forms of diphenhydramine and epinephrine;
5. Vaccines indicated for public health needs; and
6. Tuberculin test material.

(B) The agency shall have policies and procedures that address –

1. Specific drugs authorized to be possessed by the agency and the nurse;
2. Indications for use of the drugs possessed;
3. Receiving orders from an authorized prescriber for drug administration;
4. Leaving drugs with the patient for routine care

procedures;

5. Conditions for storing and transporting of the drugs by the agency and the nurse; and

6. Quantity of drugs possessed by the agency and the nurse.

(C) The nurse must have authorization from an authorized prescriber, such as an individual patient order, protocol or standing order, to administer the drugs.

(D) Up to a two- (2-) week supply of sodium chloride, water, and heparin may be left with the patient provided the patient or the patient's representative has been instructed verbally or in writing on how to perform the procedure. Drugs left with the patient shall be labeled with instructions for use. A record shall be made of all drugs left with the patient in the patient's medical record. Drugs left with the patient may not be returned to the agency.

(E) Drugs may be stored at the agency or transported by the nurse, and shall be stored or transported at all times in accordance with the manufacturer's storage requirements. Except as otherwise authorized by subsection (2)(C) of this rule, refrigerator units used by the agency for storing drugs shall not be used for storing non-drug items.

(F) All drugs must be received from a licensed pharmacy or drug distributor. The quantity of drugs possessed by an agency shall be limited to that necessary to meet the needs of the agency's patient population for two (2) weeks.

(6) In addition to the other requirements of this rule, a Class I pharmacy within a residence must be located in a physically separate room that has a door with a suitable lock. Patients are not allowed in a Class I pharmacy located within a residence. Class I pharmacies may be inspected by the board as authorized by law, including Class I pharmacies located in a residence. The permit holder must arrange for a designated representative to be present for inspection, if requested by the board. Other than a Class I pharmacy, no pharmacy permit will be issued to a location that is located in a residence regardless of zoning.

(7) Except as otherwise authorized by law, a licensee, permittee, or registrant of the board must cooperate with any investigation or inspection conducted by or on the board's behalf. Cooperation includes responding fully and promptly to questions, providing copies of records as requested, executing releases for records as requested, allowing photographs or digital image capture of any facility licensed or permitted by the board, and appearing at interviews, hearings, or meetings scheduled by the board or the board's authorized designee.

(8) Exemptions. At its discretion, the board may grant an exemption to the facility requirements of this rule for a time period designated by the board if such exemption is not contrary to law and the exemption will provide equal or greater protection of the public safety, health, or welfare. Exemption requests must be submitted in writing and identify the specific exemption requested, the grounds for exemption, the requested exemption length, and proposed procedures or safeguards for protecting the public safety, health, or welfare if the exemption is approved.

AUTHORITY: sections 338.240 and 338.280, RSMo 2016, and sections 338.010, 338.140, and 338.210, RSMo Supp. 2021. This rule originally filed as 4 CSR 220-2.010. Original rule filed July 18, 1962, effective July 28, 1962. Amended: Filed Nov. 9, 1966, effective Nov. 19, 1966. Amended: Filed Oct. 27, 1970, effective Nov. 6, 1970. Amended: Filed Dec. 31, 1975, effective Jan. 10, 1976. Amended: Filed May 21, 1979, effective Nov. 12, 1979. Amended: Filed April 14, 1982, effective July 11, 1982. Amended: Filed April 16, 1985, effective Sept. 27, 1985. Amended: Filed Nov. 4, 1985, effective March 13, 1986. Amended: Filed Dec. 15, 1987, effective April 28, 1988. Amended: Filed Oct. 12, 1988, effective March 11, 1989. Amended: Filed Jan. 30, 1991, effective July 8, 1991. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed June 29, 1999, effective Jan. 30, 2000. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed July 24, 2001, effective Feb. 28, 2002. Amended: Filed Feb. 18, 2003, effective Sept. 30, 2003. Amended: Filed May 13, 2005, effective Oct. 30, 2005. Moved to 20 CSR 2220-2.010, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008. ** Amended: Filed Jan. 20, 2022, effective Aug. 30, 2022.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019, 2021; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

***Pursuant to Executive Order 21-07, 20 CSR 2220-2.010, subsections (1)(A) and (1)(B) was suspended from March 20, 2020 through August 5, 2021.*

20 CSR 2220-2.011 Electronic Final Product Verification (Pharmacists)

PURPOSE: This rule establishes requirements for electronic final product verification by a pharmacist using qualifying technology.

(1) Pharmacist Verification. A Missouri licensed pharmacist may use an electronic verification system to verify the accuracy of a final prescription/medication order, provided –

(A) The electronic verification system allows the pharmacist to see an exact, clear, and unobstructed visual image or images of the filled prescription/medication order contents and the label affixed to the container. If multiple units are being dispensed, the pharmacist must be able to see and verify an image or images of each unit and each individual affixed label. A mechanism must be in place to record or communicate the pharmacist's verification approval;

(B) The identity of the pharmacist responsible for verifying the final product is documented in the pharmacy's records as required by 20 CSR 2220-2.080;

(C) Pharmacy technicians and intern pharmacists assisting the pharmacist with electronic verification must be trained and competent to perform the duties assigned and have a documented initial and annual assessment of competency using the pharmacy's approved electronic verification system;

(D) No further manipulation of the prescription/medication order occurs after the pharmacist's electronic verification is complete other than applying the required container lid or seal. For purposes of this section, manipulation does not include preparing a finished prescription/medication order for mailing, delivery, or storage; and

(E) Except as otherwise provided by law, compounded preparations cannot be verified via an electronic verification system. Compounded preparations must be personally verified by a pharmacist.

(2) Technology Requirements. Electronic verification systems must be maintained in good working order and must provide a clear, unobstructed visual image or images of the filled prescription/medication order contents and the affixed label for each individual prescription or medication order. Use of the electronic verification system must be terminated if the system

is not properly functioning and the root cause identified and corrected before further use. Prior to dispensing, a pharmacist shall review and authorize overrides performed by a pharmacy technician or intern pharmacist of any technology generated errors, warnings, alerts, or exceptions related to system functioning or medication verification/accuracy. Documentation of the pharmacist's review and authorization must be maintained in the pharmacy's records.

(A) The electronic verification system must be implemented and validated by a pharmacist prior to initial use to confirm proper functioning. The system must be revalidated by a pharmacist in accordance with the pharmacy's policies and procedures.

(B) Proof of compliance with validation/revalidation requirements must be documented and maintained in the pharmacy's records, including but not limited to the identity of the pharmacist performing the required validation/testing and validation/testing date(s) and results.

(3) Quality Assurance. Pharmacies using an electronic verification system as authorized by this rule must maintain an ongoing and documented quality assurance system that monitors the performance of the electronic verification system and the electronic assisted verification process to ensure proper and accurate functioning. The quality assurance system must include procedures for reporting dispensing errors and system malfunctions.

(4) Policies and Procedures. Pharmacies utilizing an electronic verification system pursuant to this rule must maintain current, written policies and procedures governing all aspects of electronic-assisted verification activities, including, but not limited to:

(A) Staff training and competency assessments;

(B) Operation of the quality assurance system, including reporting, investigating and addressing errors, system malfunctions, and other quality assurance issues;

(C) Testing, validation, and revalidation of electronic verification technology to ensure proper functioning; and

(D) System maintenance, including any routine or preventative maintenance.

(5) Recordkeeping. Except as otherwise provided herein, records required by this rule must be maintained electronically or in writing by the pharmacy for a minimum of two (2) years. Records must be made available for inspection or copying, and produced to the board or the board's authorized designee upon request.

(6) The provisions of this rule do not modify, amend, or supersede any provisions of law governing pharmacy technician or intern pharmacist supervision requirements.

AUTHORITY: sections 338.140 and 338.210, RSMo Supp. 2021, and sections 338.240, 338.280, and 338.400, RSMo 2016. Original rule filed Feb. 9, 2022, effective Aug. 30, 2022.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.240, RSMo 1951, amended 2011; 338.280, RSMo 1951, amended 1971, 1981; and 338.400, RSMo 2011.*

20 CSR 2220-2.012 Technology Assisted Prescription/ Medication Order Verification (Intern Pharmacists and Pharmacy Technicians)

PURPOSE: This rule establishes requirements for pharmacy technicians/intern pharmacists performing technology assisted prescription/medication order verification under the supervision of a pharmacist.

(1) Definitions.

(A) "Authorized intern pharmacist" – An individual who holds a current and active Missouri intern pharmacist license and has completed employer-approved training in technology assisted verification using the pharmacy's approved technology assisted verification system.

(B) "Authorized pharmacy technician" – A currently registered Missouri pharmacy technician who –

1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies;

2. Has completed employer-approved training in technology assisted verification using the pharmacy's approved technology assisted verification system; and

3. Has assisted in the practice of pharmacy as a registered/ licensed pharmacy technician in the state of Missouri or another U.S. state or territory for a minimum of one (1) year.

(C) "Technology Assisted Verification" (TAV)–The process of verification of the final prescription or medication order and affixed label by an authorized pharmacy technician or authorized intern pharmacist using a technology assisted verification system that complies with this rule.

(D) "Technology Assisted Verification System" (TAVS) – An electronic system that utilizes barcode technology or another electronic process/method to electronically verify the final medication prescription or medication order has been properly dispensed and to electronically verify the prescription/medication order has been properly labeled for the correct patient.

(2) Pharmacy Technicians/Intern Pharmacists. A Missouri-licensed pharmacist may allow an authorized pharmacy technician or authorized intern pharmacist to verify the final prescription/medication order using a TAVS if –

(A) The medication is a non-controlled substance and will be dispensed in the original manufacturer's unopened unit of use package, or the non-controlled medication has been repackaged in compliance with 20 CSR 2220-2.130 and previously verified by a pharmacist;

(B) The authorized pharmacy technician or intern pharmacist is under the supervision of a Missouri-licensed pharmacist who is physically present within the dispensing area and able to provide immediate assistance. A current list of pharmacy technicians/intern pharmacists authorized to perform TAV must be maintained at the pharmacy along with proof of the required training and competency assessment;

(C) The authorized pharmacy technician/intern pharmacist is competent to perform the duties assigned and has completed a documented initial and annual assessment of competency using the pharmacy's approved TAVS. A pharmacist may not simultaneously supervise a total of more than two (2) pharmacy technicians or intern pharmacists performing TAV as authorized by this rule. The pharmacist-in-charge may petition the board to increase the number of supervised technicians/intern pharmacists for good cause;

(D) A pharmacist verifies the accuracy of prescription/ medication order data entry prior to dispensing and completes a prospective drug utilization review. The identity of the verifying pharmacist must be recorded in the pharmacy's records as required by 20 CSR 2220-2.080;

(E) The TAVS is used to verify the proper prescription label has been affixed to the correct manufacturer unit of use package

or repacked container for the correct patient. The identity of the authorized pharmacy technician or intern pharmacist performing the TAV and the supervising pharmacist must be documented in the pharmacy's records; and

(F) No manual manipulation of the prescription/medication order occurs after the TAV occurs. For purposes of this rule, manual intervention does not include preparing a finished prescription/medication order for mailing, delivery, or storage.

(3) Technology Requirements. Technology assisted verification systems must be maintained in good working order, and must verify prescriptions/medication orders and the affixed labels with one hundred percent (100%) accuracy. Use of the TAVS must be terminated and the root cause identified and corrected if a verification error is detected. Only a pharmacist shall be authorized to initiate the operation of a TAVS or override any technology generated errors, warnings, alerts, or exceptions related to TAVS functioning or medication verification/accuracy.

(A) The TAVS must be implemented and validated by a pharmacist prior to initial use to confirm the technology's accuracy and correctness. At a minimum, the TAVS must complete one thousand (1,000) consecutive product verifications during the initial validation process with a one hundred percent (100%) accuracy rate. A pharmacist must audit one hundred percent (100%) of product verifications completed during the initial validation process before dispensing and confirm accuracy. The required pharmacist audit may not be delegated to an intern pharmacist or a pharmacy technician.

(B) A pharmacist must conduct daily random quality testing on a sample size of prescriptions verified by the TAVS. The required sample size shall not be less than two percent (2%) of prescriptions/medication orders verified via the TAVS on the last day of system operation. Use of the TAVS must be terminated and the root cause identified and corrected if quality testing results show less than one hundred percent (100%) accuracy.

(C) A TAVS must be revalidated by a pharmacist in accordance with the pharmacy's policies and procedures.

(D) The required revalidation process must include a sampling of prescriptions/medication order verifications by the TAVS using a sample size that is sufficient to confirm the technology is properly and accurately functioning. A pharmacist must audit and verify one hundred percent (100%) accuracy of the sampled verifications prior to further use of the TAVS. The required pharmacist audit may not be delegated to an intern pharmacist or a pharmacy technician.

(E) Proof of compliance with validation, revalidation, and testing requirements must be documented and maintained in the pharmacy's records, including but not limited to the name, initials, or identification code(s) of the pharmacist performing the required validation/testing and validation/testing date(s) and results.

(5) Quality Assurance. Pharmacies using TAV as authorized by this rule must maintain an ongoing and documented quality assurance system that monitors the performance of the TAVS and the TAV process to ensure proper and accurate functioning. The quality assurance system must include procedures for reporting dispensing errors, system malfunctions, or other compliance concerns. Notification of any dispensing error involving a TAV that reaches the patient must be submitted to the board electronically or in writing within ten (10) days of discovery. The required notification must include the date of the incident, patient name, the technician or intern pharmacist who performed the TAV, a description of the error, the applicable prescription/medication order number or unique identifier, and the supervising pharmacist of record.

(6) Policies and Procedures. Pharmacies using TAV must maintain current, written policies and procedures governing all aspects of technology assisted verification activities, including but not limited to –

(A) Staff training and competency assessments;

(B) Operation of the required quality assurance system, including reporting, investigating, and addressing errors, system malfunctions, and other quality assurance issues;

(C) Testing, validation, and revalidation of the TAVS to ensure proper functioning; and

(D) System maintenance, including any routine or preventative maintenance.

(7) Recordkeeping. Records required by this rule must be maintained by the pharmacy electronically or in writing for a minimum of two (2) years. Records must be made available for inspection or copying and produced to the board or the board's authorized designee upon request.

(8) Applicability. Compliance with this rule is not required if a pharmacist physically verifies the final prescription/medication order and the affixed label before dispensing. Final prescription/medication order verification for a Class R Remote Dispensing Site pharmacy must comply with 20 CSR 2220-2.680.

AUTHORITY: sections 338.140 and 338.210, RSMo Supp. 2021, and sections 338.240, 338.280, and 338.400, RSMo 2016. Original rule filed Feb. 9, 2022, effective Aug. 30, 2022.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.240, RSMo 1951, amended 2011; 338.280, RSMo 1951, amended 1971, 1981; and 338.400, RSMo 2011.*

20 CSR 2220-2.013 Prescription Delivery Requirements

PURPOSE: This rule establishes requirements for authorized prescription delivery sites.

(1) Every pharmacy delivering prescription drugs shall develop and implement written policies and procedures to ensure the safe and appropriate delivery of prescription drugs within the temperature requirements recommended by the manufacturer or the *United States Pharmacopeia* (USP). Except as otherwise provided herein, prescriptions filled by a Missouri licensed pharmacy may not be left at, accepted by, or delivered to a location, place of business or entity not licensed as a pharmacy.

(2) At the request of the patient or the patient's authorized designee, licensees may deliver a filled prescription for an individual patient directly to the patient or the patient's authorized designee or to –

(A) The office of a licensed health care practitioner authorized to prescribe medication in the state of Missouri;

(B) A long-term care facility as defined by 20 CSR 2220-2.140 where the patient resides;

(C) A hospital, office, clinic, or other medical institution that provides health care services;

(D) A residence designated by the patient or the patient's authorized designee; or

(E) The patient's office or place of employment.

(3) At the request of a customer, legally filled prescriptions for veterinary use may be delivered to a residence, business, or clinic designated by the customer.

(4) Licensees shall comply with all applicable controlled substance laws and regulations, including, but not limited to, all applicable security requirements.

(5) Returns of medication delivered pursuant to this section shall be governed by, and handled in accordance with, Chapter 338, RSMo, and the rules of the board.

AUTHORITY: section 338.280, RSMo 2000, and sections 338.095, 338.100, 338.140, and 338.240, RSMo Supp. 2011. Original rule filed May 14, 2012, effective Nov. 30, 2012.*

**Original authority: 338.095, RSMo 1993, amended 2007; 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.015 Termination of Business as a Pharmacy

PURPOSE: This rule establishes guidelines for the termination of business as a pharmacy.

(1) A licensed pharmacy who plans to terminate business activities shall file a written notice with the State Board of Pharmacy. The written notice shall be submitted to the State Board of Pharmacy in person or by registered or certified mail within fifteen (15) days after the date of termination. This notice shall be made on a form provided by the board or in letter form from the licensee and shall include the following information:

(A) The name, address, license (permit) number and effective date of closing;

(B) The name, address, and license (permit) number of the entity to which any of the stock/inventory will be transferred;

(C) The name and address of the location to which records, required to be maintained by law, have been transferred.

1. Any records that are transferred to an unlicensed location must be retrievable for board review within seven (7) working days of a request made by an authorized official of the board.

2. Any records that are transferred to a licensed (permitted) pharmacy or licensed drug distributor must be maintained in accordance with record requirements as set forth in section 338.100, RSMo.

(2) The licensee (permit holder) terminating business may transfer all drugs and records in accordance with the following:

(A) On the date of termination, a complete inventory of all controlled substances being transferred or disposed of shall be completed according to state and federal laws. This inventory shall serve as the final inventory of the pharmacy terminating business and as the initial inventory of the licensed entity to which the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee or permit holder involved in the transfer.

(B) A pharmacy terminating business shall not transfer misbranded, outdated or adulterated drugs, except for purposes of proper disposal; and

(C) Upon the actual termination of business, the license (permit) of the pharmacy shall be returned to the State Board of Pharmacy for cancellation either in person or by registered or certified mail.

(3) A one (1)-time transfer of drugs and devices due to a termination of business that is in compliance with this rule will not require a pharmacy to seek licensure as a drug distributor under sections 338.330 and 338.333, RSMo.

(4) The requirements of this rule are not intended to replace or be in conflict with any other laws or regulations governing the appropriate licensure, change of ownership or change of location of a pharmacy.

(5) The termination date is the date on which the permit holder ceases to practice pharmacy as defined in sections 338.010 and 338.210, RSMo, at the permitted location.

AUTHORITY: sections 338.210 and 338.280, RSMo 1994. This rule originally filed as 4 CSR 220-2.015. Original rule filed May 4, 1995, effective Dec. 30, 1995. Moved to 20 CSR 2220-2.015, effective Aug. 28, 2006.*

**Original authority: 338.210, RSMo 1951 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.016 Pharmacy Operations During an Emergency or Declared Disaster

PURPOSE: This rule establishes guidelines for temporary pharmacy operations during an emergency or declared disaster.

(1) Definitions.

(A) "Disaster Area" – A specified geographical area within the state that has been designated by the governor or federal authorities as an area that has been adversely affected by a natural or man-made disaster and that requires extraordinary measures to provide adequate, safe, and effective health care for the affected population.

(B) "Emergency Situation" – An emergency caused by a natural or man-made disaster that substantially prevents a Missouri licensed pharmacy from providing pharmacy services at the pharmacy's permitted location.

(C) "Home Pharmacy" – A Missouri licensed pharmacy that operates or applies for an emergency temporary pharmacy permit pursuant to this rule.

(D) "Emergency Declaration" – A state or federally declared emergency or disaster that impacts Missouri patients.

(2) Emergency Situations. A pharmacy that is substantially unable to provide pharmacy services at their permitted location due to an emergency situation may file a change of location application with the board to provide pharmacy services at a temporary site. No application fee shall apply. The location change must be approved by the board prior to changing locations and the designated location must successfully pass a board inspection.

(A) Approval of a temporary change of location under this rule will be based on the need, type, and scope of the emergency situation, as well as the ability of the pharmacy to ensure proper security and comply with state and federal drug laws.

(B) Unless otherwise approved by the board for good cause, temporary pharmacy permits shall be valid for up to six (6) months, if requested. A change of location application is required if the pharmacy will be operating at a temporary location for more than the allowed six (6) months or desires to permanently remain at the temporary site.

(C) The board may waive designated facility or pharmacy

operational requirements at a temporary location to prevent the interruption of pharmacy services. Waiver requests must be submitted in writing and must demonstrate how the permit holder will maintain patient safety and ensure adequate security.

(D) A change of location application must be filed with the board when the home pharmacy is ready to return to their original permitted location. No fee will apply. The permitted location must pass a board inspection prior to resuming pharmacy services at the original location.

(E) Records must be maintained as required by Chapter 338, RSMo, and the rules of the board.

(F) Approval of a temporary location change does not interfere with any rights or privileges of a pharmacy permit holder at the original pharmacy location, or prevent a permit holder from applying for a change of location as outlined in the board's rules.

(3) Emergency Declarations/Disaster Areas. A Missouri licensed pharmacy located in Missouri may apply for an emergency temporary pharmacy permit to provide pharmacy services to Missouri patients impacted by an emergency declaration or located in a disaster area. Applications for an emergency temporary pharmacy permit must be submitted on a form provided by the board with the applicable fee, and must demonstrate that the temporary pharmacy is needed to ensure adequate pharmacy services are reasonably available for impacted patients. The following additional requirements apply, unless otherwise approved by the board:

(A) The temporary pharmacy permit shall be considered part of the home pharmacy's permit and not a separate pharmacy permit. The home pharmacy and the temporary pharmacy must have the same pharmacist-in-charge. The home pharmacy is responsible for ensuring compliance with all applicable state and federal law at a temporary pharmacy licensed under this rule;

(B) Unless otherwise approved by the board, temporary pharmacy permits will only be approved for a designated location and for the pharmacy classifications authorized on the home pharmacy's permit prior to the declared disaster or emergency declaration;

(C) Approval of an emergency temporary pharmacy permit will be based on the need, type, and scope of emergency or disaster, as well as the pharmacy's ability to maintain proper security and comply with applicable state and federal law, including, section 338.240, RSMo;

(D) The temporary location must successfully pass a board inspection before a temporary pharmacy permit is issued. Additionally, temporary pharmacies must be available for inspection, as requested by the board or the board's authorized designee;

(E) The board may waive designated facility or pharmacy operational requirements to prevent the interruption of pharmacy services at an emergency temporary pharmacy. Waiver requests must be submitted in writing and must demonstrate how the permit holder will maintain patient safety and adequate pharmacy security, if approved. Controlled substances must be handled and dispensed in accordance with state and federal law;

(F) Temporary pharmacy permits issued under this section are valid for thirty (30) days but may be renewed at the discretion of the board. To renew, the home pharmacy must file a written request with the board and demonstrate that renewal of the temporary pharmacy permit is needed to protect the public health and ensure access to pharmacy services;

(G) Temporary pharmacies approved under this section must terminate services on the expiration date approved by the board or within five (5) days after the disaster area designation or emergency declaration is withdrawn or terminated, whichever is earlier; and

(H) Records must be maintained as required by Chapter 338, RSMo, and the rules of the board. Required records must be maintained at the home pharmacy after the temporary pharmacy permit closes, and must be available for inspection or copying by the board or the board's authorized designee.

AUTHORITY: sections 338.043 and 338.280, RSMo 2016, and sections 338.210, 338.220, and 338.333, RSMo Supp. 2020. This rule originally filed as 4 CSR 220-2.016. Original rule filed May 4, 1995, effective Dec. 30, 1995. Moved to 20 CSR 2220-2.016, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Nov. 30, 2019. Rescinded and readopted: Filed April 8, 2021, effective Oct. 30, 2021.*

**Original authority: 338.043, RSMo 1990, amended 1997, 2001; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014, 2020; 338.280, RSMo 1951, amended 1971, 1981; and 338.333, RSMo 1989, amended 2010, 2012, 2018.*

20 CSR 2220-2.017 Non-Electronic (Manual) Prescription Records

PURPOSE: This rule establishes requirements for non-electronic (manual) prescription record keeping.

(1) Pharmacies that maintain a non-electronic prescription record system shall maintain the following information in its system for each original and refilled prescription:

(A) The date the prescription was prescribed and the date of initial dispensing, if different;

(B) A unique, sequential prescription label number;

(C) If applicable, a unique readily retrievable identifier;

(D) The name of the patient(s), or if an animal, species and owner's name;

(E) The prescriber's name, if an oral prescription, signature if a written or faxed prescription. Electronic signatures shall comply with all applicable provisions of 20 CSR 2220-2.085;

(F) Name, strength and dosage of drug, device or poison dispensed and the directions for use;

(G) The number of refills authorized;

(H) The quantity dispensed in weight, volume, or number of units;

(I) The date of refill, if any;

(J) The identity of the pharmacist responsible for reviewing the accuracy of data on each original prescription;

(K) The identity of the pharmacist responsible for verifying the final product prior to dispensing on each original and refill prescription, if different;

(L) Whether generic substitution has been authorized by the prescriber;

(M) Any change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug;

(N) The address of the prescriber and the patient when the prescription is for a controlled substance;

(O) The prescriber's Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance; and

(P) If additional refills are authorized and added to the prescription, a notation indicating the method and source of the authorization must be a part of the manual record or hard copy, in such case the expiration date of the original prescription shall remain the same; and

(Q) Any prescription, when it is for a controlled substance, must comply with all requirements of federal and state controlled substance laws.

(2) The information specified in section (1) shall be required and recorded on all prescriptions prior to dispensing by a pharmacist/pharmacy.

(3) Prescription hard copies must be maintained and filed sequentially by the prescription label number or a unique readily retrievable identifier. Except as otherwise provided by 20 CSR 2220-2.010(1)(J), prescription hard copies shall be retrievable at the time of inspection.

AUTHORITY: sections 338.095, 338.100, 338.140, and 338.240, RSMo Supp. 2012, and section 338.280, RSMo 2000. Original rule filed Jan. 10, 2013, effective Aug. 30, 2013.*

**Original authority: 338.095, RSMo 1993, amended 2007; 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.240, RSMo 1951, amended 2011.*

20 CSR 2220-2.018 Prescription Requirements

PURPOSE: This rule establishes requirements for information required on prescriptions.

(1) To be valid for purposes of dispensing, a prescription shall conform to all requirements of sections 338.056 or 338.196, RSMo, and shall contain the following information:

(A) The date of prescribing;

(B) The name of the patient(s), or if an animal, species and owner's name;

(C) The prescriber's name, if an oral prescription, or written or electronic signature if a written, faxed, or an electronically transmitted prescription. Electronic signatures shall comply with all applicable provisions of 20 CSR 2220-2.085;

(D) Name, strength and dosage of drug, device or poison prescribed and the directions for use;

(E) The number of refills, if applicable;

(F) The quantity prescribed in weight, volume, or number of units;

(G) An indication of whether generic substitution has been authorized by the prescriber, as required by section 338.056, RSMo;

(H) Any change or alteration made to the prescription dispensed based on contact with the prescriber to show a clear audit trail. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug;

(I) The address of the prescriber and the patient when the prescription is for a controlled substance;

(J) The prescriber's Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance; and

(K) Controlled substance prescriptions shall also comply with all requirements of federal and state controlled substance laws.

AUTHORITY: sections 338.095, 338.100, 338.140, and 338.240, RSMo Supp. 2012, and section 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.018. Original rule filed May 4, 1995, effective Dec. 30, 1995. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Moved to 20 CSR 2220-2.018, effective Aug. 28, 2006. Amended: Filed Jan. 10, 2013, effective Aug. 30, 2013.*

**Original authority: 338.095, RSMo 1993, amended 2007; 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.240, RSMo 1951, amended 2011.*

20 CSR 2220-2.020 Pharmacy Permits

PURPOSE: This rule outlines the requirements for obtaining and maintaining a pharmacy permit.

(1) All permits for the operation of a pharmacy shall expire on the date specified by the director of the Division of Professional Registration pursuant to 20 CSR 2231-2.010.

(2) A pharmacy permit may be issued on the application of the owners. If the owner is a corporation, an officer of the corporation must sign the application as the applicant. If the owner is a partnership, a partner must sign the application as the applicant. If the owner is a limited liability partnership, a general partner must sign the application as the applicant. If the owner is a limited liability company, a member must sign the application as the applicant. In the case where a pharmacy is owned and operated by a person(s) who is a licensed pharmacist and in active charge of the pharmacy, the application for permit can be made by either party. Alternatively, a pharmacy permit application may be signed by an attorney or other person lawfully granted power of attorney to sign the application on the applicant's behalf. In such case, a representative of the applicant shall review the application for truth and accuracy prior to submitting the application to the board. Proof of a power of attorney designation shall be submitted with the application.

(A) An application for a pharmacy permit will become null and void if the applicant fails to complete the process for licensure within six (6) months of receipt of the application by the board.

(3) When a pharmacy changes ownership, the original permit becomes void on the effective date of the change of ownership. Before any new business entity resulting from the change opens a pharmacy for business, it must obtain a new permit from the board. A temporary license shall be issued once a completed application and fee have been received by the board. The effective date of the temporary license may be the date the change of ownership is listed as effective on the application. Such license shall remain in effect until a permanent license is issued or denied by the board.

(A) A change of ownership of a pharmacy owned by a sole proprietor is deemed to have occurred when –

1. The business is sold and the sale becomes final;

2. The proprietor enters into a partnership with another individual or business entity; or

3. The proprietor dies; provided, however, that the proprietor's estate may continue to operate the pharmacy under the licensed pharmacist in good standing in this state, but in no case for a period of more than one (1) year and only so long as appropriate pharmacy permit fees are paid.

(B) If a corporation owns a pharmacy, it is not necessary to obtain a new license if the owners of the stock change. If a limited liability partnership or a limited liability company

owns a pharmacy, it is not necessary to obtain a new license if the partners or members of the company change, as long as the partnership or company is not dissolved by that change. It is necessary to file written notice with the State Board of Pharmacy within ten (10) days after a change occurs in partners in a limited liability partnership, or in members in a limited liability company. This notification must be in writing and certified. However, when a corporation, limited liability partnership, or limited liability company begins ownership of a pharmacy or transfers ownership of a pharmacy, a new license must be obtained regardless of the relationship between the previous and subsequent owners.

(C) All individuals or business entities owning twenty-five percent (25%) or more of the ownership of any entity owning a pharmacy must notify the board within thirty (30) days of acquiring the percentage.

(4) If an individual or business entity operating a pharmacy changes the location of the pharmacy to a new facility (structure), the pharmacy shall not open for business at the new location until the board or its duly authorized agent has inspected the premises of the new location and approved it and the pharmacy as being in compliance with section 338.240, RSMo and all other provisions of the law. Upon the approval and receipt of a change of location fee, the board shall issue a permit authorizing operation of a pharmacy at the new location, and the permit shall bear the same number as the previous pharmacy permit. However, the permit remains valid if the pharmacy address changes, but not the location, and an amended permit will be issued without charge under these circumstances.

(A) Remodeling of a licensed pharmacy within an existing structure shall be deemed to have occurred when any change in the storage conditions of the Schedule II controlled substances is made or new connections to water/sewer resources are made or any changes in the overall physical security of drugs stored in the pharmacy as defined in 20 CSR 2220-2.010(1)(H) are made. Remodeling as defined within this section will not require the initiation of any change of location procedures. Satisfactory evidence of plans for any remodeling of a pharmacy must be provided to the board office thirty (30) days in advance of commencing such changes along with an affidavit showing any changes to the pharmacy physical plant and the projected completion date for any remodeling.

(5) Permits, when issued, will bear an original number. Permits must be posted in a conspicuous place in the pharmacy to which it is issued.

(6) No pharmacy permit will be issued unless the pharmacy area is under the direct supervision of a licensed pharmacist in good standing with the Missouri State Board of Pharmacy who is designated as the pharmacist-in-charge and meets the requirements of 20 CSR 2220-2.090.

(7) If the owner/applicant is not the licensed pharmacist-in-charge, then the pharmacist-in-charge must meet the requirements of 20 CSR 2220-2.090 and complete the pharmacist-in-charge affidavit of the permit application.

(8) The names of all pharmacists regularly working in a pharmacy shall be clearly displayed on the premises of every establishment having a pharmacy permit.

(9) The following classes of pharmacy permits or licenses are hereby established for entities providing services as defined in section 338.010, RSMo:

(A) Class A: Community/Ambulatory. A pharmacy that provides services as defined in section 338.010, RSMo to the general public;

(B) Class B: Hospital Pharmacy. A pharmacy owned, managed, or operated by a hospital as defined by section 197.020, RSMo, or a clinic or facility under common control, management, or ownership of the same hospital or hospital system. This section shall not be construed to require a Class B hospital pharmacy permit or license for hospitals solely providing services within the practice of pharmacy under the jurisdiction of, and the licensure granted by, the Department of Health and Senior Services under and pursuant to Chapter 197, RSMo;

(C) Class C: Long-Term Care. A pharmacy that provides services as defined in section 338.010, RSMo by the dispensing of drugs and devices to patients residing within long-term care facilities. A long-term care facility means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients;

(D) Class D: Non-Sterile Compounding. A pharmacy that provides services as defined in section 338.010, RSMo and provides a non-sterile compounded product as defined in 20 CSR 2220-2.400(1) and meets the following criteria:

1. Any product made from any bulk active ingredient in a batch quantity as defined in 20 CSR 2220-2.400(3);

(E) Class E: Radiopharmaceutical. A pharmacy that is not open to the general public and provides services as defined in section 338.010, RSMo that prepares and dispenses radioactive drugs as defined by the Food and Drug Administration (FDA) and drugs related to the use of radioactive drugs to health care providers for use in the treatment or diagnosis of disease and that maintains a qualified nuclear pharmacist as the pharmacist-in-charge;

(F) Class F: Renal Dialysis. A pharmacy that is not open to the general public that provides services as defined in section 338.010, RSMo limited to the dispensing of renal dialysis solutions and other drugs and devices associated with dialysis care;

(G) Class G: Medical Gas. A pharmacy that provides services as defined in section 338.010, RSMo through the provision of oxygen and other prescription gases for therapeutic uses;

(H) Class H: Sterile Product Compounding. A pharmacy that provides services as defined in section 338.010, RSMo, and provides a sterile pharmaceutical as defined in 20 CSR 2220-2.200;

(I) Class I: Consultant. A location where any activity defined in section 338.010, RSMo is conducted, but which does not include the procurement, storage, possession or ownership of any drugs from the location;

(J) Class J: Shared Service. A pharmacy engaged in the processing of a request from another pharmacy to fill or refill a prescription drug order, or that performs or assists in the performance of functions associated with the dispensing process, drug utilization review (DUR), claims adjudication, refill authorizations, and therapeutic interventions;

(K) Class K: Internet. A pharmacy that provides services as defined in section 338.010, RSMo, and is involved in the receipt, review, preparation, compounding, dispensing, or offering for sale any drugs, chemicals, medicines, or poisons for any new prescriptions originating from the Internet for greater than ninety percent (90%) of the total new prescription volume on any day;

(L) Class L: Veterinary. A pharmacy engaged in the sale, dispensing, or filling of a legend drug for use in animals that must only be dispensed by prescription under state or federal law, provided that an additional Class L pharmacy permit shall

not be required for pharmacies holding a Class A pharmacy permit that are also engaged in the sale, dispensing, or filling of a legend drug for animal use;

(M) Class M: Specialty (bleeding disorder). A pharmacy that provides blood-clotting products and ancillary infusion equipment or supplies to patients with bleeding disorders, as defined by 20 CSR 2220-6.100;

(N) Class N: Automated dispensing system (health care facility). An automated dispensing system as defined in 20 CSR 2220-2.900 that is located in a facility where medical services are provided to patients on the premises of or at the same physical location as such facility;

(O) Class O: Automated dispensing system (ambulatory care). An automated dispensing system as defined in 20 CSR 2220-2.900 that is not located in a healthcare facility identified in subsection (9)(N) of this rule; and

(P) Class P: Practitioner office/clinic. A pharmacy that is located in or on the premises of an office or clinic of a healthcare practitioner licensed in the United States who is authorized to prescribe medication by law and that provides pharmacy services as defined in section 338.010, RSMo, solely for patients of such practitioner or practitioners.

(10) Pharmacy applications for initial licensure or renewals of a license shall accurately note each class of pharmacy that is practiced at the location noted on the application or renewal thereof. The permit (license) issued by the board shall list each class of licensure that the pharmacy is approved to engage in. A Pharmacy Change of Classification Application shall be filed with the board prior to adding or deleting any pharmacy classes with the applicable fee.

(11) Prescriptions processed by any classification of licensed pharmacy must be provided by a practitioner licensed in the United States, authorized by law to prescribe drugs, and who has performed a medical evaluation of the patient as required by law. A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order for such drug was issued on the basis of an Internet-based questionnaire or without a valid pre-existing patient-practitioner relationship.

AUTHORITY: section 338.140, RSMo Supp. 2013, and section 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.020. Original rule filed July 18, 1962, effective July 28, 1962. Amended: Filed Nov. 9, 1966, effective Nov. 19, 1966. Amended: Filed Oct. 27, 1970, effective Nov. 6, 1970. Amended: Filed Dec. 31, 1975, effective Jan. 10, 1976. Emergency amendment filed July 15, 1981, effective Sept. 28, 1981, expired Nov. 11, 1981. Amended: Filed Aug. 10, 1981, effective Nov. 12, 1981. Amended: Filed April 14, 1982, effective July 11, 1982. Amended: Filed March 14, 1983, effective June 11, 1983. Amended: Filed Feb. 11, 1985, effective May 11, 1985. Amended: Filed Dec. 16, 1985, effective May 11, 1986. Amended: Filed Aug. 1, 1986, effective Nov. 13, 1986. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed Jan. 6, 1998, effective Aug. 30, 1998. Amended: Filed June 29, 1999, effective Jan. 30, 2000. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 30, 2001, effective June 30, 2002. Amended: Filed Dec. 3, 2002, effective June 30, 2003. Amended: Filed May 13, 2005, effective Oct. 30, 2005. Moved to 20 CSR 2220-2.020, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007. Emergency amendment filed Jan. 19, 2016, effective Feb. 2, 2016, expired July 30, 2016. Amended: Filed Jan. 19, 2016, effective July 30, 2016.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.025 Nonresident Pharmacies

PURPOSE: This rule establishes licensure guidelines for nonresident pharmacies.

(1) Nonresident pharmacies shall not ship, mail, or deliver prescription drugs into Missouri without first obtaining a pharmacy license from the Missouri Board of Pharmacy. An exemption to licensure is allowed when a nonresident pharmacy provides a prescription drug in an emergency situation or supplies lawful refills to a patient from a prescription that was originally filled and delivered to a patient within the state in which the nonresident pharmacy is located.

(2) To obtain a Missouri pharmacy license, a nonresident pharmacy must –

(A) Maintain a pharmacy license in good standing from the state in which the nonresident pharmacy is located;

(B) Submit an application as provided by the Missouri Board of Pharmacy for licensure in compliance with 20 CSR 2220-2.020(2), (3), (9), and (10);

(C) Pay all appropriate licensing fees;

(D) Submit a copy of the state pharmacy license from the state in which the nonresident pharmacy is located;

(E) If controlled substances will be shipped into Missouri, submit a copy of the applicant's federal controlled substance registration and, if applicable, a copy of the applicant's state controlled substance registration from the state where the applicant is located;

(F) If the designated pharmacist-in-charge does not have a current and active Missouri pharmacist license issued by the board, submit an official verification from the state board of pharmacy or equivalent state pharmacist licensing agency verifying that the designated pharmacist-in-charge holds a current and active pharmacist license in the state in which the nonresident pharmacy is located; and

(G) Submit a copy of the applicant's most recent pharmacy inspection by the applicant's resident state board of pharmacy or its equivalent state regulatory body. The inspection must have occurred within the last eighteen (18) months for sterile compounding pharmacy applicants or within the last twenty-four (24) months for all other pharmacy applicants. If a state inspection is unavailable, an inspection by the Missouri Board of Pharmacy or from the Verified Pharmacy Program (VPP) of the National Association of State Boards of Pharmacy or a similar inspection by an entity approved by the board may be accepted.

(3) Each nonresident pharmacy shall supply any inspection reports, warning notices, notice of deficiency reports, or any other related reports requested by the board or the board's authorized designee to review compliance with state and federal drug laws.

(4) The Missouri Board of Pharmacy will extend reciprocal cooperation to any state that licenses and regulates nonresident pharmacies for the purpose of investigating complaints against pharmacies located in Missouri or the sharing of information and investigative reports, as long as the other state will extend the same reciprocal cooperation to the Missouri Board of Pharmacy.

AUTHORITY: sections 338.140, 338.210.4, 338.220, 338.240, and 338.280, RSMo 2016. This rule originally filed as 4 CSR 220-2.025. Original rule filed Jan. 16, 1990, effective May 11, 1990. Amended:*

Filed June 28, 2002, effective Jan. 30, 2003. Moved to 20 CSR 2220-2.025, effective Aug. 28, 2006. Amended: Filed Oct. 10, 2017, effective April 30, 2018.

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.210, RSMo 1951, amended 2001, 2011; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.030 Educational and Licensing Requirements
(Rescinded August 30, 2013)

AUTHORITY: sections 338.020, 338.040, 338.070, 338.140, and 338.280, RSMo 2000, and sections 338.030 and 338.035, RSMo Supp. 2007. This rule originally filed as 4 CSR 220-2.030. This version of rule filed July 18, 1962, effective July 28, 1962. Amended: Filed Nov. 9, 1966, effective Nov. 19, 1966. Amended: Filed Nov. 27, 1967, effective Dec. 7, 1967. Amended: Filed Sept. 30, 1969, effective Oct. 10, 1969. Amended: Filed Dec. 31, 1975, effective Jan. 10, 1976. Emergency amendment filed July 15, 1981, effective Sept. 28, 1981, expired Nov. 11, 1981. Amended: Filed Aug. 10, 1981, effective Nov. 12, 1981. Amended: Filed April 14, 1982, effective July 11, 1982. Amended: Filed Dec. 12, 1983, effective May 11, 1984. Amended: Filed Dec. 11, 1984, effective March 11, 1985. Amended: Filed June 14, 1985, effective Aug. 26, 1985. Amended: Filed Feb. 25, 1986, effective June 12, 1986. Amended: Filed Oct. 1, 1987, effective Jan. 29, 1988. Amended: Filed Jan. 3, 1990, effective April 26, 1990. Amended: Filed Jan. 30, 1991, effective July 8, 1991. Amended: Filed Jan. 3, 1992, effective June 25, 1992. Amended: Filed Aug. 4, 1992, effective April 8, 1993. Amended: Filed Sept. 26, 1994, effective March 30, 1995. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed March 19, 1996, effective Oct. 30, 1996. Amended: Filed Dec. 9, 1996, effective July 30, 1997. Amended: Filed April 23, 1998, effective Nov. 30, 1998. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed June 28, 2002, effective Jan. 30, 2003. Amended: Filed Nov. 13, 2002, effective June 30, 2003. Amended: Filed Dec. 1, 2004, effective June 30, 2005. Moved to 20 CSR 2220-2.030, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008. Rescinded: Filed Jan. 10, 2013, effective Aug. 30, 2013.

20 CSR 2220-2.032 Licensure by Examination for Graduates of Nonapproved Foreign Pharmacy Schools
(Rescinded August 30, 2013)

AUTHORITY: sections 338.020, 338.030, and 338.140, RSMo 2000. This rule originally filed as 4 CSR 220-2.032. Original rule filed Oct. 16, 1985, effective Feb. 24, 1986. Amended: Filed Dec. 24, 1990, effective June 10, 1991. Amended: Filed Dec 15, 1995, effective July 30, 1996. Amended: Filed Nov. 21, 1997, effective June 30, 1998. Amended: Filed March 1, 2001, effective Sept. 30, 2001. Moved to 20 CSR 2220-2.032, effective Aug. 28, 2006. Rescinded: Filed Jan. 10, 2013, effective Aug. 30, 2013.

20 CSR 2220-2.034 Licensure by Reciprocity for Graduates of Nonapproved Foreign Pharmacy Schools Who Have Been Licensed in Another State
(Rescinded August 30, 2013)

AUTHORITY: sections 338.020 and 338.030, RSMo Supp. 1990. This rule originally filed as 4 CSR 220-2.034. Original rule filed Oct. 16, 1985, effective Feb. 24, 1986. Amended: Filed Aug. 29, 1986, effective Dec. 25, 1986. Amended: Filed Dec. 24, 1990, effective June 10, 1991. Moved to 20 CSR 2220-2.034, effective Aug. 28, 2006. Rescinded: Filed Jan. 10, 2013, effective Aug. 30, 2013.

20 CSR 2220-2.036 Temporary License
(Rescinded August 30, 2013)

AUTHORITY: section 338.140, RSMo 2000, and section 338.043, RSMo Supp. 2007. This rule originally filed as 4 CSR 220-2.036. Original rule filed May 24, 1993, effective Dec. 9, 1993. Amended: Filed Nov. 21, 1997, effective June 30, 1998. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Moved to 20 CSR 2220-2.036, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008. Rescinded: Filed Jan. 10, 2013, effective Aug. 30, 2013.

20 CSR 2220-2.050 Public Complaint Handling and Disposition Procedure

PURPOSE: This rule establishes a procedure for the receipt, handling and disposition of public complaints by the board, pursuant to the mandate of section 620.010.16(6), RSMo.

(1) Any member of the public, the profession or any federal, state, or local official may make and file a complaint with the board. No member of the State Board of Pharmacy shall file a complaint with this board while s/he holds that office, unless that member excuses him/herself from further board deliberations or activity concerning the matters alleged within that complaint. Any staff member or employee of the board may file a complaint pursuant to this rule in the same manner as any member of the public.

(2) Complaints should be mailed or delivered to the following address: State Board of Pharmacy, 3605 Missouri Blvd., PO Box 625, Jefferson City, MO 65102. Complaints may be based upon personal knowledge or upon information and belief.

(3) Except as otherwise authorized by the board or executive director, all complaints shall be made in writing and identify their maker by name and address. Complaints may be made on forms provided by the board, which are available upon request. Complaints need not be made by affidavit, but oral or telephone communications will not be considered or processed as complaints unless otherwise authorized by the board or the executive director. Any staff member or employee of the board may make and file a complaint based upon information and belief, in reliance upon oral, telephone, or written but unsigned communications received by the board, unless those communications are believed by that staff member or employee to be false.

(4) Each complaint received under this rule shall be recorded by the board in consecutive order as received. The record shall contain each complainant's name and address; the name and address of the subject(s) of the complaint; the date each complaint is received by the board; a brief statement of the acts complained of, and the ultimate disposition of the complaint. This record shall be a closed record of the board.

(5) The complainant shall be informed in writing as to whether the complaint has been dismissed by the board or is being referred to legal counsel for legal action. The complainant may be notified of the ultimate disposition of the complaint, excluding judicial appeals and may be provided with a

copy of the decisions (if any) of the Administrative Hearing Commission and the board. The provisions of this section do not apply to complaints filed by staff members or employees of the board, based upon information and belief, acting in reliance on third-party information received by the board.

(6) Both the complaint and any information obtained as a result of the complaint investigation are a closed record of the board and shall not be available for inspection by the public.

(7) This rule does not limit the board's authority to file a complaint with the Administrative Hearing Commission or with a court, charging a licensee, permittee, or other person or entity with any actionable conduct or violation, whether or not this complaint exceeds the scope of the acts charged in a preliminary public complaint filed with the board and whether or not any public complaint has been filed with the board.

(8) The board interprets this rule, which is required by law, to exist for the benefit of those members of the public who submit complaints to the board. This rule is not deemed to protect, or to inure to the benefit of those licensees, permit holders, registrants, or other persons or entities against whom the board has instituted or may institute administrative or judicial proceedings concerning possible violations of provisions of Chapter 338, RSMo.

(9) To facilitate the investigation, evaluation, and disposition of complaints, which involve violations of federal and state law governing controlled substances, the Board of Pharmacy may designate Bureau of Narcotics and Dangerous Drugs personnel and other state personnel as pharmacy inspectors. These inspectors shall be authorized pursuant to section 338.150, RSMo to enter and inspect various premises.

(10) Persons designated by the Board of Pharmacy as pharmacy inspectors and other Board of Pharmacy personnel may attend board meetings in order to assist the board in its deliberations.

AUTHORITY: section 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-2.050. Original rule filed Jan. 11, 1982, effective June 1, 1982. Amended: Filed Aug. 27, 1985, effective Nov. 11, 1985. Amended: Filed Aug. 29, 1986, effective Dec. 25, 1986. Amended: Filed Sept. 26, 1994, effective March 30, 1995. Amended: Filed June 28, 2002, effective Jan. 30, 2003. Amended: Filed May 13, 2005, effective Oct. 30, 2005. Moved to 20 CSR 2220-2.050, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Nov. 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.060 Gold Certificates

PURPOSE: This rule sets requirements concerning the issuance of honorary gold certificates to pharmacists licensed in Missouri for fifty (50) years.

(1) The Missouri Board of Pharmacy shall issue gold certificates to all pharmacist licensees who have been regularly licensed as pharmacists in Missouri for fifty (50) years without charge to the recipient. Gold certificates are honorific in nature and confer no right to practice pharmacy upon the recipient.

AUTHORITY: section 338.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-2.060. Original rule filed March 14, 1983, effective June 11, 1983. Moved to 20 CSR 2220-2.060, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Nov. 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019.*

20 CSR 2220-2.080 Electronic Prescription Records

PURPOSE: This rule establishes requirements for utilizing an electronic data-processing system in a pharmacy.

(1) In lieu of a non-electronic (manual) record-keeping system, a pharmacy may elect to maintain an electronic data processing (EDP) record keeping-system. All information concerning the compounding, dispensing, or selling by a pharmacy of any drug, device, or poison pursuant to a lawful prescription which is entered into an EDP system at any pharmacy shall be entered only by a licensed pharmacist or by a technician or intern pharmacist under the direct supervision and review of a licensed pharmacist. Prior to dispensing, a pharmacist shall personally verify the accuracy of prescription data entered into the EDP for each original prescription. The EDP system shall comply with all applicable state and federal controlled substance laws and regulations.

(2) EDP systems shall comply with the requirements of section 338.100, RSMo, and capable of storing and retrieving the following information concerning the original filling or refilling of any prescription:

(A) A unique, sequential prescription label number;

(B) If applicable, a unique readily retrievable identifier;

(C) Date the prescription was prescribed;

(D) The date the prescription was initially filled and the date of each refill;

(E) Patient's full name, or if an animal, the species and owner's name;

(F) Patient's address or animal owner's address when a prescription prescribes a controlled substance;

(G) Prescriber's full name;

(H) Prescriber's address and Drug Enforcement Administration (DEA) number when a prescription specifies a controlled substance;

(I) Name, strength, and dosage of drug, device, or poison dispensed and any directions for use;

(J) Quantity originally dispensed;

(K) Quantity dispensed on each refill;

(L) Identity of the pharmacist responsible for verifying the accuracy of prescription data prior to dispensing on each original prescription;

(M) Identity of the pharmacist responsible for reviewing the final product prior to dispensing on each original and refill prescription, if different from the pharmacist verifying prescription data;

(N) The number of authorized refills and quantity remaining;

(O) Whether generic substitution has been authorized by the prescriber;

(P) The manner in which the prescription was received by the pharmacy (e.g., written, telephone, electronic, or faxed); and

(Q) Any other change or alteration made in the original prescription based on contact with the prescriber to show a clear audit trail including, but not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug.

(3) The information specified in section (2) shall be required and recorded in the EDP system prior to dispensing by a pharmacist or pharmacy.

(4) Except as otherwise provided by 20 CSR 2220-2.083, prescription hard copies must be maintained and filed by either the sequential prescription label number or by a unique readily retrievable identifier. For verbal, telephone, or electronic prescriptions, a hard copy representation of the prescription shall be made and filed which contains all of the information in section (2). Prescription hard copies must be retrievable at the time of inspection, except as otherwise provided by 20 CSR 2220-2.010(1)(J). For purposes of this subsection an "electronic prescription" is defined as provided in 20 CSR 2220-2.085.

(5) If additional refills are authorized and added to a prescription, a notation indicating the method and source of the authorization must be a part of the EDP record or hard copy, in that case the expiration date of the original prescription shall remain the same.

(6) Any hospital pharmacy using an EDP system licensed by the board, as described in section (1), for outpatient prescriptions, employee prescriptions, and take-home prescriptions shall conform to all sections of this rule.

(7) Any EDP system must be capable of producing the record required by this rule and said records shall be readily retrievable online. Readily retrievable is defined as providing EDP records immediately or within two (2) hours of a request by an inspector or by making a computer terminal available to the inspector for immediate use.

(8) An auxiliary record-keeping system shall be established for the documentation of refills if the EDP system is inoperative for any reason. The auxiliary system shall ensure that all refills are authorized by the original prescription or prescriber. When this EDP system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the EDP system within seven (7) working days. However, nothing in this section precludes the pharmacist from using his/her professional judgment for the benefit of a patient's health and safety.

(9) If a prescription is transferred from a pharmacy using an EDP system, a notation or deactivation must be made on the transferred record to preclude any further dispensing. If the same prescription is transferred back into the original pharmacy, it shall be treated as a new record, showing the original date written and expiration date.

(10) Prior to or simultaneously with the purging of any EDP system, the permit holder shall make certain that a record of all prescription activity being erased exists in readable form, either on paper, microfiche, or electronic media storage. A pharmacy that desires to discard hard copy prescriptions that are more than three (3) years old must maintain all prescription information on microfiche or electronic media. Any process utilizing microfiche must ensure that all data is available and in readable form. Any pharmacy opting for the utilization of microfiche records must also maintain a microfiche reader so that records may be reviewed on-site by pharmacy personnel or board inspectors. Electronic media storage is defined as any medium such as a computer, floppy disk or diskette, compact disk (CD), or other electronic device that can reproduce all prescription information as required by section 338.100, RSMo, and this rule and is retrievable within three (3) working days.

(11) If coded information exists in the electronic EDP, the board inspector may request the definitions of the codes from the pharmacist on duty for immediate review.

(12) The EDP system shall be able to provide a listing of drug utilization by date for any drug for a minimum of the preceding twenty-four- (24-) month period that includes the specific drug product, patient name, or practitioner. If requested to do so, the pharmacy shall have three (3) working days to provide the report.

(13) The provisions of this rule do not preempt any federal laws or regulations. If any part of this rule is declared invalid by a court of law, that declaration shall not affect the other parts of the rule.

(14) Licensees shall also comply with all state and federal controlled substance record keeping requirements, including, any required daily log books or printouts.

AUTHORITY: sections 338.100 and 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-2.080. Original rule filed March 8, 1984, effective Aug. 11, 1984. Amended: Filed Nov. 4, 1985, effective Feb. 24, 1986. Rescinded and readopted: Filed Dec. 5, 1988, effective March 11, 1989. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Moved to 20 CSR 2220-2.080, effective Aug. 28, 2006. Amended: Filed Jan. 10, 2013, effective Aug. 30, 2013. Amended: Filed May 13, 2019, effective Nov. 30, 2019.*

**Original authority: 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010, 2016; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.083 Electronic Record-Keeping Systems

PURPOSE: The purpose of this rule is to establish requirements and guidelines for maintaining prescription hard copies in an electronic record-keeping system.

(1) In lieu of maintaining the original prescription hard copy or a hard copy representation as required by 20 CSR 2220-2.018 or 20 CSR 2220-2.080, a pharmacy shall be authorized to maintain an exact digitized image of the prescription in an electronic record-keeping system (ERS). For purposes of this rule, an electronic record-keeping system is defined as a system maintained by the pharmacy that provides input, storage, processing, communications, output, and control functions for digitized images of original prescriptions. Any alterations to the digitized original prescription shall be documented as required by 20 CSR 2220-2.018 or 20 CSR 2220-2.080, as applicable.

(2) Controlled substance hard copy prescriptions shall be maintained as required by applicable state and federal law.

(3) Digitized prescription images shall be readily retrievable by the pharmacy. Readily retrievable shall be defined as providing records immediately or within two (2) hours of a request of the inspector or by making a computer terminal available to the inspector for immediate use. An ERS system shall be capable of printing and retrieving the digitized prescription image at the time of inspection, including the

reverse side of the prescription if applicable. Any printout of a digitized prescription image provided by a licensee/registrant to the patient or the patient's representative shall be conspicuously marked with the statement "Copy Only – Not Valid for Dispensing Purposes."

(4) Pharmacies maintaining an ERS shall establish written policies and procedures for the use of the ERS which shall include policies and procedures for reviewing compliance with the requirements of this rule and for storing, retrieving, and recovering digitized images. The policy and procedure manual shall be reviewed annually and shall be available to representatives of the board upon request.

(5) All digitized images in the ERS shall be stored, copied, or saved onto secure storage media on a regular basis in a manner that will allow image recovery in the event of a disaster, system interruption, or system failure.

AUTHORITY: sections 338.100 and 338.140, RSMo Supp. 2012. Original rule filed Jan. 10, 2013, effective Aug. 30, 2013.*

**Original authority: 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010 and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011.*

20 CSR 2220-2.085 Electronic Prescriptions and Medication Orders

PURPOSE: This rule establishes guidelines for electronic prescriptions and medication orders.

(1) Definitions.

(A) Electronic image transmission – An exact visual image of a paper prescription or medication order that is electronically received by a pharmacy from a licensed prescriber or the prescriber's authorized agent (e.g., a facsimile/scan).

(B) Electronic prescription – Any prescription or medication order, other than an electronic image transmission, which is electronically transmitted from a licensed prescriber or the prescriber's authorized agent to a pharmacy.

(C) Electronic signature – An exact electronic replica of the prescriber's signature or a confidential digital key code, number, or other identifier attached to or logically associated with a record that is executed or adopted by a prescriber with the intent to sign the record.

(2) Prescriptions or medication orders may be transmitted to a pharmacy by the prescriber or the prescriber's authorized agent as an electronic image transmission or an electronic prescription.

(A) Electronic image transmissions and electronic prescriptions must contain all information required by state and federal law, including, designation of whether generic substitution is authorized. Electronic image transmissions must be formatted as required by section 338.056, RSMo, and bear the prescriber's manual or electronic signature.

(B) Controlled substance prescriptions and medication orders must comply with state and federal controlled substance laws and regulations and must be signed in accordance with state and federal law.

(C) A pharmacist shall be responsible for verifying the authenticity of any electronic image transmission or electronic prescription prior to dispensing by taking measures which, in his/her professional judgment, may be necessary to ensure the prescription or medication order was initiated or authorized by the prescriber.

(3) In lieu of a manually signed prescription or medication order, a pharmacist may accept a paper prescription or medication order with an electronic signature if the prescription/medication order is applied to paper that utilizes security features that will detect or otherwise identify if the prescription/medication order is subject to any form of copying and/or alteration.

AUTHORITY: sections 338.095, 338.140, and 338.280, RSMo 2016, and section 338.010, RSMo Supp. 2017. This rule originally filed as 4 CSR 220-2.085. Original rule filed Sept. 25, 1995, effective April 30, 1996. Amended: Filed July 28, 2000, effective Jan. 30, 2001. Amended: Filed April 16, 2001, effective Nov. 30, 2001. Moved to 20 CSR 2220-2.085, effective Aug. 28, 2006. Amended: Filed Dec. 15, 2017, effective June 30, 2018.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017; 338.095, RSMo 1993, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 328.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.090 Pharmacist-in-Charge

PURPOSE: This rule defines the term pharmacist-in-charge, sets the requirements and standards for this title, and defines the term full-time pharmacy.

(1) Except as otherwise authorized by law, each pharmacy shall designate a pharmacist-in-charge who is responsible for managing pharmacy compliance and supervising pharmacy staff. At a minimum, the pharmacist-in-charge shall assist the permit holder in ensuring pharmacy operations and clinical activities comply with the rules of the board and all applicable state and federal law governing pharmacy practice.

(A) The pharmacist-in-charge must be regularly involved in, and engaged with, pharmacy operations and monitoring pharmacy compliance. Except in the event of an emergency or other urgent need, the pharmacist-in-charge must be consulted and given an opportunity to provide input prior to implementation of any pharmacy policy, procedure, system, or practice that will modify or expand the delivery of pharmacy services.

(B) The pharmacist-in-charge must be physically present at the pharmacy for a sufficient amount of time as needed to effectively supervise pharmacy activities and ensure pharmacy compliance. Additionally, the permit holder must provide the pharmacist-in-charge designated time to review pharmacy compliance on a regular basis while not engaged in medication dispensing or providing patient services.

(C) The pharmacist-in-charge must have authority to temporarily suspend or restrict pharmacy operations or the activity of licensees/registrants, if deemed reasonably necessary or appropriate to ensure pharmacy compliance or the safe provision of pharmacy services, pending final direction or approval from the permit holder.

(D) The permit holder must have policies and procedures in place for regularly reviewing staffing and resource needs with the pharmacist-in-charge, including policies and procedures for requesting additional staff or staffing modifications.

(2) A pharmacist must immediately notify the board electronically or in writing on a form designated by the board if he/she stops serving as the designated pharmacist-in-charge. At or immediately prior to a pharmacist-in-charge change, a

controlled substance inventory must be taken by a designee of the permit holder that complies with state and federal controlled substance inventory requirements, including 21 CFR 1304.11. The signature of the individual(s) taking the required inventory must be documented on the inventory.

(3) This rule does not exempt a permit holder from responsibility for compliance with applicable state or federal law.

AUTHORITY: sections 338.240 and 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2021. This rule originally filed as 4 CSR 220-2.090. Emergency rule filed April 12, 1984, effective April 22, 1984, expired Aug. 20, 1984. Original rule filed April 12, 1984, effective Aug. 11, 1984. Amended: Filed Feb. 25, 1986, effective Aug. 11, 1986. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed Aug. 21, 1998, effective Feb. 28, 1999. Amended: Filed Dec. 30, 1998, effective June 30, 1999. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Moved to 20 CSR 2220-2.090, effective Aug. 28, 2006. Amended: Filed Jan. 20, 2022, effective Aug. 30, 2022.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.095 Collection of Medication for Destruction

PURPOSE: The purpose of this rule is to authorize pharmacies to collect medication for purposes of destruction and to establish requirements for medication collection programs.

(1) Missouri licensed pharmacies may collect medication from the public for destruction in compliance with this rule. Pharmacies collecting controlled substances shall comply with all applicable state and federal controlled substance laws. Pharmacies collecting non-controlled substances shall comply with sections (2) to (9) of this rule. Participation in a medication return or destruction program is voluntary. This rule shall not be construed to require that a licensee or permit holder participate in or establish a return/destruction program.

(2) Definitions. The following definitions shall apply for purposes of this rule:

(A) "Mail"- Mail shall include mailing via the United States Postal Service or shipping via a common carrier; and

(B) "Nonretrievable"- For the purposes of destruction, a condition or state to which medication is rendered after undergoing a process that permanently alters the medication's physical condition or state through irreversible means and thereby renders the medication unavailable and unusable for all practical purposes.

(3) Pharmacies may maintain a collection receptacle or establish an authorized mail-back program to collect non-controlled medication from the general public for destruction. Collection receptacles may not be used to dispose of unused/unwanted medication in the pharmacy's inventory (e.g., outdated drugs, medical waste). Collected medication shall not be resold or reused.

(A) Pharmacies collecting medication under this rule shall develop and implement written policies and procedures governing medication collection which must include, but not be limited to, authorized destruction procedures and methods.

(B) This rule does not preempt or modify return/reuse of medication as authorized by 20 CSR 2220-3.040, the provisions of Chapter 196, RSMo, governing the Prescription Drug Repository Program, or any provision of state or federal law governing controlled substances or the destruction, handling, or transporting of medical or pharmaceutical waste.

(4) Collection Receptacles. Pharmacies that maintain a collection receptacle to collect non-controlled medication for destruction must comply with the following:

(A) Collection receptacles must be securely placed and maintained inside the physical building of the pharmacy in a manner that prevents theft, diversion, or unauthorized removal. Receptacles must be securely fastened to a permanent structure. The receptacle must be visible to pharmacy staff at all times and shall not be located in or near exit doors;

(B) The receptacle must be a securely locked, substantially constructed container with a permanent outer container, and must contain an inner liner that complies with this rule. The receptacle must have an opening that allows medication to be added to the inner liner but does not allow the contents of the inner liner to be removed. The opening must be locked or otherwise made inaccessible to the public so that drugs cannot be deposited into the collection receptacle when the pharmacy is closed for business;

(C) A sign must be prominently displayed on the outer container of the receptacle indicating that only non-controlled substances may be deposited into the receptacle. If the receptacle is also used to collect controlled substances, the required sign must comply with state and federal controlled substance laws;

(D) Inner liners must be removable, waterproof, tamper-evident, and tear-resistant and must bear a permanent, unique identification number or identifier that enables the inner liner to be tracked. The contents of the inner liner shall not be viewable from the outside;

(E) Inner liners must be installed or removed from a collection receptacle by or under the supervision of at least two (2) board licensees or registrants. Inner liners must be immediately sealed once removed from the receptacle; the sealed inner liner shall not be opened, x-rayed, analyzed, or otherwise penetrated by the pharmacy or pharmacy staff. After removal, sealed inner liners pending destruction may be stored at the pharmacy in a securely locked, substantially constructed cabinet or in a securely locked room or area with controlled access for no more than thirty (30) business days; and

(F) Pharmacies must report any theft or diversion of or from a collection receptacle to the board in writing within fourteen (14) days in a manner designated by the board.

(5) Mail-Back Programs. Pharmacies may provide mail-back packages to the public for the purpose of mailing medication to a collector that is authorized by the Drug Enforcement Administration or federal law to receive prescription medication for destruction ("an authorized collector"). Packages may be provided directly by the pharmacy or the pharmacy's authorized designee, provided the pharmacy is responsible for ensuring compliance with this section.

(A) Mail-back packages must be preaddressed with the address of the authorized collector. The cost of shipping the package shall be postage or otherwise prepaid. Licensees/permit holders shall not accept any returned mail-back packages. Packages must be mailed directly to the authorized collector by the consumer or his/her agent.

(B) Mail-back packages must be nondescript and shall not include any markings or other information that might indicate that the package contains medication. Packages must be

water-proof, spill-proof, tamper-evident, tear-resistant, and sealable.

(C) Mail-back packages must be provided with instructions for mailing, notice that packages may only be mailed from within the fifty (50) United States or US territories, and notice that only packages provided by or on behalf of the pharmacy may be used to mail medication.

(D) Senders shall not be required to provide any personally identifiable information when mailing back medication.

(E) Mail-back packages must include a unique identification number or other unique identifier that enables the package to be tracked.

(6) Long-Term Care Facilities. Pharmacies may provide and maintain a collection receptacle at a long-term care facility to collect medication from the public or facility residents for destruction. This section does not apply to medication collected for return and reuse as authorized by 20 CSR 2220-3.040.

(A) Collection receptacles must be securely placed and maintained inside the physical building of the long-term care facility in a manner that prevents theft, diversion, or unauthorized removal. Receptacles must be securely fastened to a permanent structure and must be visible to the facility's staff at all times. In lieu of fastening to a permanent structure, receptacles that are not accessible to the public or residents may be stored in a securely locked room or area with controlled access that is restricted to facility staff/personnel until transfer to the pharmacy. Collection receptacles shall not be located in or near exit doors.

(B) Collection receptacles must be a securely locked, substantially constructed container with a permanent outer container, and must contain an inner liner that complies with subsections (4)(D) and (E) of this rule. The receptacle must have an opening that allows medication to be added to the inner liner but does not allow the contents of the inner liner to be removed. The opening must be locked or otherwise made inaccessible to the public so that drugs cannot be deposited into the collection receptacle when the facility is closed for business.

(C) If the receptacle is accessible to the public or residents, a sign must be prominently displayed on the outer container of the receptacle indicating that only non-controlled substances may be deposited into the receptacle. The required sign must comply with state and federal controlled substance laws if the receptacle is also used to collect controlled substances.

(D) The pharmacy shall be responsible for installing, managing, and maintaining the receptacle and for the removal, sealing, transfer, and storage of inner liners and receptacle contents.

(E) Inner liners may only be installed, removed, and transferred either: 1) by or under the supervision of two (2) board licensees or registrants acting on behalf of the pharmacy; or 2) by or under the supervision of a board licensee/registrant and an employee/staff member of the long-term care facility designated by the pharmacy (e.g., a supervisory charge nurse).

(F) After removal, sealed inner liners may be stored at the facility in a securely locked, substantially constructed cabinet or in a securely locked room or area with controlled access for no more than three (3) business days.

(7) Destruction Methods. Medication collected for destruction shall be rendered nonretrievable and destroyed in compliance with all applicable federal and state laws. Medication shall be destroyed in one (1) of the following ways:

(A) On-site Destruction: Medication may be destroyed on the physical premises of the pharmacy, provided two (2) board licensees or registrants must personally witness the destruction of the medication and handle or observe the handling of the medication until the substance is rendered non-retrievable; or

(B) Transfer to an Authorized Entity: Collected medication may be mailed, shipped, or transferred to an entity authorized to destroy the medication off-site, provided two (2) board licensees or registrants must witness or observe the mailing, shipping, or transfer. If medication is transported by the pharmacy to the off-site location, the medication must be constantly moving towards its final location. Unnecessary and unrelated stops and stops of an extended duration shall not occur.

(8) Records. Except as otherwise provided herein, pharmacies shall maintain a complete and accurate record of the following for two (2) years:

(A) Inventories. Pharmacies shall conduct an inventory every twelve (12) months of inner-liners that are present at the pharmacy or at a long-term care facility that are unused or awaiting destruction. The inventory shall be documented in writing and must include:

1. The date of the inventory;

2. The number of inner liners present on the date of the inventory and the size of any inner liners (e.g., five (5) ten- (10-) gallon liners, etc.);

3. The unique identification number/identifier of each inner liner, whether unused or awaiting destruction;

(B) Inner Liners. The pharmacy must maintain the following written records for inner liners:

1. The unique identification number/identifier and the size of each unused inner liner (e.g., five- (5-) gallon, ten- (10-) gallon, etc.);

2. The date each inner liner is installed, the address of the location where each liner is installed, the unique identification number/identifier and size of each installed inner liner, and the names and signatures of the two (2) required witnesses for each installation; and

3. The date each inner liner is removed and sealed, the unique identification number/identifier of each removed inner liner, and the names and signatures of the two (2) required witnesses for each removal; and

(C) Destruction. The pharmacy must maintain the following written records:

1. For medication destroyed on-site of the pharmacy, the date and method of destruction, the unique identification number/identifier of each inner liner destroyed, and the names and signatures of the two (2) required witnesses of the destruction.

2. For medication destroyed off-site, the date each inner liner was transferred for destruction, the name and address of each entity to whom each sealed inner liner was transferred for destruction, the unique identification number/identifier of each inner liner transferred for destruction, and the name of the two (2) required witnesses for medication transfer or transport.

(9) Law Enforcement Return Programs. Licensees/permitholders shall be exempt from compliance with this rule when participating in medication collection programs conducted by local, state, or federal law enforcement agencies provided –

(A) Collected medication is placed into a collection container or area that is under the supervision of law enforcement personnel at all times;

(B) Law enforcement personnel are present whenever drugs

are collected or on-site; and

(C) The licensee/permitholder does not take possession of the collected medications. Collected medications must remain under the control of, and must be removed by, law enforcement.

AUTHORITY: sections 338.140, 338.240, 338.280, and 338.315, RSMo 2016. Original rule filed Aug. 30, 2016, effective March 30, 2017.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.240, RSMo 1951, amended 2011; 338.280, RSMo 1951, amended 1971, 1981; and 338.315, RSMo 1989, amended 2011, 2012, 2014.*

20 CSR 2220-2.100 Continuing Pharmacy Education
(Rescinded August 30, 2013)

AUTHORITY: sections 338.060 and 338.140, RSMo 2000. This rule originally filed as 4 CSR 220-2.100. Original rule filed Nov. 9, 1984, effective April 11, 1985. Amended: Filed Nov. 21, 1997, effective June 30, 1998. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed June 28, 2002, effective Jan. 30, 2003. Amended: Filed April 1, 2004, effective Sept. 30, 2004. Amended: Filed June 15, 2005, effective Jan. 30, 2006. Moved to 20 CSR 2220-2.100, effective Aug. 28, 2006. Rescinded: Filed Jan. 10, 2013, effective Aug. 30, 2013.

20 CSR 2220-2.110 PRN Refills

PURPOSE: This rule clarifies the board's requirements for refills as needed so that the practicing pharmacists in Missouri will have adequate guidelines in this area.

(1) A pharmacist shall not fill or refill any prescription which was written more than one (1) year before being presented to the pharmacist, unless the pharmacist consults with the prescriber and confirms –

(A) That the person for whom the drugs or medicines were prescribed is still under the prescriber's care or treatment;

(B) That the prescriber desires for the person to continue receiving the drugs or medicines; or

(C) If the prescriber answers negatively in either case listed in subsection (1)(A) or (B), the pharmacist shall not fill or refill the prescription, even if the prescription authorizes refills as needed (PRN).

(2) If a pharmacist knows or has reason to believe that a person for whom a prescription has been written is not under the prescribers care or treatment at the time the prescription is presented for filling or refilling, the pharmacist shall consult with their prescriber and ascertain that the prescriber intends for the person to receive the drugs or medicines. The pharmacist shall do this no matter when the prescription originally was written and even if the prescription authorizes refills PRN.

(3) After the pharmacist has confirmed the information required in sections (1) and (2) of this rule, s/he shall record it in his/her records in a uniform fashion so as to make it readily available for verification by the board or its authorized agents.

AUTHORITY: section 338.280, RSMo 1994. This rule originally filed as 4 CSR 220-2.110. Original rule filed Dec. 11, 1984, effective March 11, 1985. Moved to 20 CSR 2220-2.110, effective Aug. 28, 2006.*

**Original authority: 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.120 Transfer of Prescription or Medication Order Information

PURPOSE: This rule defines record-keeping required for transfer of prescription or medication order information.

(1) A valid new or refill prescription or medication order may be transferred to another pharmacy if –

(A) The prescription, medication order, and/or refills were authorized by the prescriber;

(B) The prescription or medication order and/or refills have not exceeded the maximum allowable time limit;

(C) If refills are involved, the number of lawfully allowable refills has not been exceeded;

(D) If the transfer involves a controlled substance, all information must be transferred directly between two (2) licensed pharmacists and comply with all applicable state and federal controlled substance laws and regulations; and

(E) The transfer of information for a controlled substance is permissible between pharmacies on a one- (1-) time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(2) The following record-keeping is required when a prescription, medication order, or refill is transferred:

(A) The prescription record at the transferring pharmacy must show –

1. The word void must appear on the face of the invalidated prescription for pharmacies using a manual record-keeping system. For pharmacies using an electronic data processing system, the prescription or medication order must be promptly voided within the system;

2. The name and location of the pharmacy to which it was transferred, the date of transfer, and the identity of the persons transferring and receiving information; and

3. If the transfer involves a controlled substance, the receiving pharmacy's address and Drug Enforcement Administration (DEA) registration number and the full name of the pharmacist(s) transferring and receiving the prescription information; and

(B) The record at the receiving pharmacy shall show all of the following, in addition to all other lawfully required information:

1. An indication that the prescription or medication order is a transfer;

2. Date of issuance;

3. Date of first dispensing;

4. Number of refills originally authorized and the number of remaining refills;

5. Date of last refill;

6. Prescription number or other unique identifier;

7. The name and location of the pharmacy that transferred the prescription or medication order;

8. The identity of the individuals transferring and receiving the information;

9. If the transfer involves a controlled substance, the transferring pharmacy's address and DEA registration number and the full names of the pharmacists transferring and receiving the prescription or medication order information; and

10. If the transfer involves information for a prescription or medication order that has never been dispensed, the date

of first dispensing, the date of last refill, and the prescription number/unique identifier are not required.

(3) An electronic transfer of prescription or medication order between licensed pharmacies must meet all of the requirements of this rule. However, licensed pharmacies that share the same electronic database and are under the same ownership are not required to record the identities of the persons receiving and transferring non-controlled information.

(4) A Class-C Long Term Care pharmacy may transfer a non-controlled prescription or medication order to a second pharmacy for the purpose of the initial dispensing of up to a seventy-two- (72-) hour medication supply to a long-term care facility patient without voiding the remaining prescription. The transferring pharmacy must deduct this amount from the remaining prescription or medication order but is not required to void it.

(5) A prescription or medication order must be transferred within one (1) business day of receiving a transfer request directly from a patient or their caretaker. All other transfer requests must be completed in a timely manner, provided licensees/permit holders shall ensure no interruption in patient therapy.

AUTHORITY: sections 338.100 and 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2020. This rule originally filed as 4 CSR 220-2.120. Original rule filed April 16, 1985, effective Aug. 11, 1985. Amended: Filed May 2, 1989, effective Aug. 24, 1989. Amended: Filed April 23, 1998, effective Nov. 30, 1998. Amended: Filed July 28, 2000, effective Jan. 30, 2001. Moved to 20 CSR 2220-2.120, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008. Amended: Filed April 11, 2019, effective Nov. 30, 2019. Amended: Filed Oct. 29, 2020, effective May 30, 2021.*

**Original authority: 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010, 2016; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.130 Drug Repackaging

PURPOSE: This rule establishes requirements for drug repackaging.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

(1) A pharmacist or pharmacy may prepackage drugs for other than immediate dispensing purposes provided that the following conditions are met:

(A) Only products which will be directly provided to the patient may be prepackaged;

(B) Containers utilized for prepackaging shall meet, as a minimum requirement, that of Class B container standards as referenced by the United States Pharmacopoeia (USP), which has been incorporated herein by reference. Where applicable, light sensitive containers shall be used;

(C) The maximum expiration date allowed for prepacked drugs shall be the manufacturer's expiration date or twelve (12) months, whichever is less; and

(D) Any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, the name of the manufacturer or distributor, an expiration date as defined in subsection (1)(C) and lot number. Pharmacies that store drugs within an automated counting device may, in place of the required label, maintain records for lot numbers and expiration dates that are required on the label as long as it is fully traceable and is readily retrievable during an inspection.

(2) The term prepacked as used in this rule is defined as any drug which has been removed from the original manufacturer's container and is placed in a dispensing container for other than immediate dispensing to a patient.

AUTHORITY: sections 338.140 and 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.130. Original rule filed Dec. 10, 1986, effective May 28, 1987. Amended: Filed Nov. 15, 1988, effective March 11, 1989. Emergency amendment filed July 1, 1991, effective July 26, 1991, expired Nov. 22, 1991. Amended: Filed July 1, 1991, effective Jan. 13, 1992. Amended: Filed July 28, 2000, effective Jan. 30, 2001. Amended: Filed Jan. 31, 2003, effective Aug. 30, 2003. Moved to 20 CSR 2220-2.130, effective Aug. 28, 2006.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.140 Prescription Services by Pharmacists/ Pharmacies for Residents in Long-Term Care Facilities

PURPOSE: This rule establishes standards for pharmacists providing prescription services to residents in long-term care facilities. The standards are directed to licensed pharmacists and pharmacies, and not to long-term care facilities.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

(1) Licensure. A pharmacist who or pharmacy which provides prescription services to a long-term care facility must be licensed to practice pharmacy in this state. A long-term care facility means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

(2) Medication Services.

(A) Policies and procedures shall be formulated to cover all packaging and dispensing responsibilities of the pharmacist/ pharmacy to the residents of the long-term care facility and shall include, at a minimum:

1. Methods used to dispense medications in a timely fashion to the facility;

2. Proper notification to the facility when a medication is

not readily available;

3. Proper labeling requirements to meet the needs of the facility and which are consistent with state and federal laws; and

4. Appropriate medication destruction, return of unused medication, or both, which is consistent with state and federal laws.

(B) Container labeling, at all times, shall conform to Chapter 338, RSMo. If a label change is required to reflect a change in directions, the pharmacist personally shall affix the correct label to the container. However, direction change labels which are defined as indicator labels that notify long-term care facility personnel that a change in directions for medication has taken place, may be used and affixed to the container by nursing home personnel in a way as not to deface the original label. Labeling of unit dose packages may be distinguished from the requirements as set forth in section 338.059, RSMo by insuring that the drug name and strength, control number and expiration date and manufacturer's name appear on the package itself. A patient's name and directions may not have to appear directly on the medication container but a mechanism should exist to identify for the personnel administering medications, what medications each patient is to receive and the directions for administration.

(C) All prescription containers, including, but not limited to, single unit, unit dose and unit-of-use containers utilized for distribution within a long-term care facility shall meet minimum requirements as referenced by the *United States Pharmacopoeia* (USP) which is incorporated herein by reference. Where applicable, light-sensitive packaging shall be used.

(3) Any drug, repackaged or prepacked that is dispensed into a long-term care facility, as defined in section (1) of this rule, in other than the manufacturer's original container, shall bear the manufacturer's expiration date or twelve (12) months, whichever is less.

(4) Remote dispensing systems are defined as any system of an automated or manual design that is used to provide doses of medication to patients for the immediate administration by authorized health care personnel and is not licensed under Chapter 338, RSMo as a pharmacy. Any medication obtained in excessive amounts shall constitute the practice of pharmacy and will require adherence to all applicable licensure and drug laws.

(A) If personnel other than a pharmacist restocks a remote dispensing system, then any drugs or other items that are to be placed within a remote dispensing system must be checked and approved by a licensed pharmacist.

(B) Any products that are repackaged for use in a remote dispensing system must comply with all provisions of 4 CSR 220-2.130.

(C) Appropriate security must be maintained over any remote dispensing system and there must be policies and procedures utilized in the delivery and storage of drugs and devices that deter misuse or theft.

(5) A prescription drug order is defined for the purpose of this rule as an order originating from a long-term care facility that is initiated by a prescriber and entered into the patient's medical record by the prescriber or qualified personnel for the purpose of initiating or renewing an order for a medication or device. All prescription drug orders shall comply with 4 CSR 220-2.018.

(A) A prescription drug order may be transferred to a licensed pharmacy for the purpose of providing an order to prepare, compound or dispense a medication or for the purpose of providing drug or medical information for use by the pharmacist in providing patient care services.

(B) In order for a generic substitution as defined in section 338.056, RSMo to take place, a prescription drug order must either comply with the prescription form as defined in section 338.056.2(1), RSMo or provide an alternate method for documenting whether a generic substitution has been authorized as determined by the long-term care medical staff. When a generic substitution is authorized and is executed by the pharmacist a clear documentation must be completed in accordance with 4 CSR 220-2.018(1)(H) and 4 CSR 220-2.080(2)(M).

(C) A pharmacy may elect to maintain a separate file system for prescription drug orders that are dispensed. When a separate file is utilized, it must comply with all applicable laws governing the maintenance and use of a prescription file by a pharmacy and the numbering system used to number prescription drug orders must be distinct from any other prescription file that is maintained.

(D) Packaging and labeling of containers shall comply with all applicable state and federal laws for any medications that leave the facility or are provided to the patient by the pharmacy for use outside the facility. Prescription drug orders issued for use within the long-term care facility are not valid for refill outside the facility.

(6) Nothing in this rule shall be deemed to constitute a waiver or abrogation of any of the provisions of Chapter 338, RSMo or other applicable provisions of state and federal laws and rules, nor should this rule be construed as authorizing or permitting any person not licensed as a pharmacist to engage in the practice of pharmacy.

(7) The provisions of this rule are declared severable. If any portion of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect unless otherwise determined by the court.

AUTHORITY: sections 338.010, 338.210, 338.240 and 338.280, RSMo 1994 and 338.140, RSMo Supp. 1999. This rule originally filed as 4 CSR 220-2.140. Original rule filed Oct. 16, 1987, effective March 25, 1988. Amended: Filed July 5, 1988, effective March 1, 1989. Amended: Filed July 19, 1991, effective Jan. 13, 1992. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed July 28, 2000, effective Jan. 30, 2001. Moved to 20 CSR 2220-2.140, effective Aug. 28, 2006.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990; 338.140, RSMo 1939, amended 1981, 1989, 1997; 338.210, RSMo 1951; 338.240, RSMo 1951; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.145 Minimum Standards for Multi-Med Dispensing

PURPOSE: This rule establishes standards for multi-med dispensing.

(1) In lieu of dispensing two (2) or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a customized patient medication package (patient med pak).

(2) A patient med pak is a package prepared by a pharmacist for a specific patient comprising one (1) or more containers and containing two (2) or more prescribed solid oral dosage forms. The patient med pak is so designed or each container is so labeled as to indicate the day and time, or period of time, that the contents within each container are to be taken.

(A) The patient med pak shall bear a label stating –

1. The name of the patient;

2. A serial number for the patient med pak itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained therein;

3. The name, strength, physical description or identification and total quantity of each drug product contained therein;

4. The directions for use and cautionary statements if any, contained in the prescription order for each drug product therein;

5. Any storage instructions or cautionary statements required by the official compendia;

6. The name of the prescriber of each drug product;

7. The date of preparation of the patient med pak and the beyond-use date assigned to the patient med pak (such beyond-use date shall be not later than ninety (90) days from the date of preparation);

8. The name, address, and telephone number of the dispenser; and

9. Any other information, statements, or warnings required for any of the drug products contained therein.

(B) If the patient med pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying each of the drug products contained therein.

(C) The patient med pak shall be accompanied by a patient package insert, in the event that any medication therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall, educational insert provided by the pharmacist for the total patient med pak.

(D) In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med pak shall comply with the moisture permeation requirements for a Class B single-unit or unit-dose container. Each container shall be either not reclosable or so designed as to show evidence of having been opened.

(E) It is the responsibility of the dispenser, when preparing a patient med pak, to take into account any applicable compendia requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the medications. In this regard, pharmacists are encouraged to report to United States Pharmacopeia (USP) headquarters any observed or reported incompatibilities.

(F) In addition to any individual prescription filing requirements, a record of each patient med pak shall be made and filed. Each record shall contain, at a minimum:

1. The name and address of the patient;

2. The serial number of the prescription order for each drug product contained therein;

3. The name of the manufacturer or labeler and lot number for each drug product contained therein;

4. Information identifying or describing the design, characteristics, or specifications of the patient med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;

5. The date of preparation of the patient med pak and the beyond-use date that was assigned;

6. Any special labeling instructions; and

7. The name or initials of the pharmacist who prepared the patient med pak.

(G) There is no special exemption for patient med paks from the requirements of the Poison Prevention Packaging Act. Thus the patient med pak, if it does not meet child-resistant standards, shall be placed in an outer package that does comply, or the necessary consent of the purchaser or physician to dispense in a container not intended to be child-resistant, shall be obtained.

(H) Once a patient med pak has been delivered to an institution or to a patient it shall not be returned to the pharmacy, unless the following requirements are met:

1. The med pak is returned to the pharmacy from which it was originally dispensed;

2. The med pak is modified/repackaged, per prescription order, for the same patient to whom it was originally dispensed;

3. The med pak is labeled in compliance with the requirements of this rule, provided the med pak shall retain the original beyond-use date assigned to the med pak before modification/repackaging;

4. The med pak is assigned a new serial number;

5. The medications removed from the med pak are destroyed in compliance with state and federal law. In no event shall medication removed from a med pak be returned to stock/inventory or dispensed to another patient; and

6. Licensees shall comply with all applicable record-keeping requirements.

(I) Multi-med paks may include controlled substances as allowed by, and in accordance with, state and federal controlled substance laws and regulations.

(J) Except as otherwise allowed in subsection (H) of this section, once a drug has been commingled with other drugs in a med pak the drug may not be returned to stock, dispensed, or distributed except for destruction purposes.

AUTHORITY: section 338.140, RSMo Supp. 2019, and section 338.280, RSMo 2016. This rule originally filed as 4 CSR 220-2.145. Original rule filed March 15, 2000, effective Sept. 30, 2000. Moved to 20 CSR 2220-2.145, effective Aug. 28, 2006. Amended: Filed Jan. 3, 2012, effective June 30, 2012. Amended: Filed Nov. 6, 2019, effective May 30, 2020.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.150 Mandatory Reporting Rule

PURPOSE: This rule defines the responsibilities of a director of pharmacy or the pharmacist-in-charge, or both, in a hospital or ambulatory surgical center in reporting disciplinary actions against pharmacist employees to the chief executive officer of the employing institution.

(1) Reports to the board from a hospital or ambulatory surgical center concerning any disciplinary action against a licensed pharmacist or the voluntary resignation of any licensed pharmacist against whom any complaints or reports have been made which might have led to final disciplinary action shall comply with section 383.133, RSMo and this rule and include at a minimum:

(A) The name, address, and telephone number of the person making the report;

(B) The name, address, and telephone number of the person who is the subject of the report;

(C) A brief description of the facts which gave rise to the issuance of the report, including the dates of occurrence deemed to necessitate the filing of the report;

(D) If court action is involved and known to the reporting agent, the identity of the court, including the date of filing and the docket number of the action;

(E) A statement as to what final action was taken by the institution; and

(F) That the report is being submitted in order to comply with the reporting provisions of Chapter 383, RSMo.

(2) Any activity that is construed to be a cause for disciplinary action according to section 338.055, RSMo or results in potential or actual harm to the public shall be deemed reportable to the board. This rule does not limit or prohibit any pharmacist from reporting a violation of the Pharmacy Practice Act directly to the Missouri Board of Pharmacy.

(3) The provisions of this rule are declared severable. If any portion of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect, unless otherwise determined by a court of competent jurisdiction.

AUTHORITY: section 383.133, RSMo 2016, and section 383.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-2.150. Original rule filed Aug. 4, 1987, effective Jan. 29, 1988. Moved to 20 CSR 2220-2.150, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Nov. 30, 2019.*

**Original authority: 383.133, RSMo 1986 and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019.*

20 CSR 2220-2.160 Definition of Disciplinary Actions

PURPOSE: This rule defines disciplinary actions which may be imposed by the Missouri Board of Pharmacy.

(1) The Missouri Board of Pharmacy may publish or cause to be published all disciplines of certificates of registration or licenses or both, including the name of the licensee, the license number, the terms of discipline and a summary of the Findings of Fact and Conclusions of Law of the Administrative Hearing Commission, in any professional journal or newsletter read by licensed pharmacists practicing in Missouri or in any newspaper of general circulation or both.

(2) The Missouri Board of Pharmacy may publicize the terms of disciplinary agreements, including the name of the licensee, the license number and a summary of the complaint, in any professional journal or newsletter read by licensed pharmacists practicing in Missouri or in any newspaper of general circulation.

(3) Any licensee whose certificate of registration, license to practice pharmacy, or both, has been revoked or suspended shall –

(A) Surrender his/her certificate of registration or license, or both, to the Missouri Board of Pharmacy to be held by the Missouri Board of Pharmacy for the duration of the suspension period;

(B) Refrain from misrepresenting the status of his/her license to practice pharmacy to any patient or to the general public; and

(C) Refrain from maintaining a physical presence in any location which is licensed as a pharmacy in Missouri during the period of suspension, except as a customer.

(4) The Missouri Board of Pharmacy may impose any other terms or requirements which, in its discretion, it may deem necessary to enforce an order of discipline.

(5) Any violation of a disciplinary order shall constitute grounds for the Missouri Board of Pharmacy to impose further discipline or terms on the licensee's certificate of registration, license to practice pharmacy, or both.

(6) Any violation of a disciplinary agreement shall constitute grounds for the Missouri Board of Pharmacy to impose a further period of discipline unless the disciplinary agreement provides otherwise.

(7) If at any time when any disciplinary sanctions have been imposed under section 338.055, RSMo or under any provision, the licensee removes him/herself from Missouri, ceases to be currently licensed under the provisions of sections 338.010–338.310, RSMo or fails to keep the Missouri Board of Pharmacy advised of his/her current place of employment and residence, the time of his/her absence or unlicensed status or unknown whereabouts may, at the discretion of the board, not be deemed or taken as any part of the time of discipline so imposed.

(8) The provisions of this rule are declared severable. If any portion of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect, unless otherwise determined by a court of competent jurisdiction.

AUTHORITY: sections 338.140, RSMo Supp. 1998 and 338.280, RSMo 1994. This rule originally filed as 4 CSR 220-2.160. Original rule filed Oct. 1, 1987, effective March 11, 1988. Amended: Filed June 29, 1999, effective Jan. 30, 2000. Moved to 20 CSR 2220-2.160, effective Aug. 28, 2006.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1986 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.165 Licensure Disciplinary Agreements

PURPOSE: This rule establishes guidelines to be used by the board for licensure disciplinary agreements.

(1) The board may elect to enter into an agreement for discipline with the holder of a pharmacist or pharmacy license for the purpose of informally resolving a complaint which the board has prepared.

(2) The use of licensure disciplinary agreements shall be subject to the following:

(A) Agreements of this type will be used at the option of the board and shall not bar the board from filing any complaints with the Administrative Hearing Commission in order to seek disciplinary action for any violation of Chapter 338, RSMo;

(B) All licensure disciplinary agreements shall contain a public notice clause which provides that the board will publish the licensing action in its quarterly newsletter and shall treat the information contained in the agreement as public information;

(C) When entering into a licensure disciplinary agreement, the board and the licensee shall waive any rights attendant to a hearing before the Administrative Hearing Commission and will consent that the licensure disciplinary agreement is in lieu of proceedings before the Administrative Hearing Commission; and

(D) If the board determines that a licensee has violated a term or condition of the agreement, or has otherwise failed to comply with the provisions of Chapter 338, RSMo, which violation would be actionable in a proceeding before the State Board of Pharmacy, the Administrative Hearing Commission, or in a circuit court, the board may elect to pursue any lawful remedies or procedures afforded to it.

(3) The provisions of this rule are declared severable. If any portion of this rule is held invalid by a court of competent jurisdiction, the remaining provisions of this rule shall remain in full force and effect unless otherwise determined by a court of competent jurisdiction.

AUTHORITY: sections 338.140, RSMo Supp. 1989 and 338.280, RSMo 1986. This rule originally filed as 4 CSR 220-2.165. Original rule filed Jan. 3, 1990, effective May 11, 1990. Amended: Filed July 19, 1991, effective Jan. 13, 1992. Moved to 20 CSR 2220-2.165, effective Aug. 28, 2006.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.170 Procedure for Impaired Pharmacist

PURPOSE: This rule establishes an efficient and timely process for the disposition of information and tentative board action concerning impaired pharmacists to the attorney general's office for purposes of preparing a complaint and streamlines the procedure utilized in interviewing pharmacists who are chemically impaired.

(1) The executive director shall receive information concerning the impairment of licensees and coordinate any investigations that seek to substantiate information concerning a possible impairment.

(2) Investigations by board inspectors or division investigators concerning chemically impaired licensees will be collected and reviewed by the executive director. Cases will be divided into two (2) categories.

(A) Category A. Chemically impaired licensees where additional information is evident that known distribution of controlled substances or legend drugs to other individuals has taken place.

(B) Category B. Chemical impairment of a licensee where controlled substances, legend drugs or alcohol have been acquired for personal use only.

(3) Cases which fall into Category A will be referred to the board for appropriate action.

(4) Cases which fall within Category B will be subject to administrative review as a preliminary action to facilitate any corrective actions deemed necessary by the board.

(5) The following shall constitute office procedures involving Category B cases:

(A) Normal procedures for completing field investigations and assimilating other pertinent information will be followed;

(B) If the director believes that a case falls into Category B of this policy, s/he shall consult with the president of the board concerning the appropriateness of an administrative review;

(C) If approval by the president is given, the director shall take actions necessary to set up a meeting with the licensee who is the subject of the investigation. In addition, other individuals such as legal counsel for the board may be asked to attend, along with any staff member, as necessary;

(D) A statement concerning due process procedures and the rights of the licensee will be read at the beginning of the review meeting. A complete record of the administrative review meeting shall be maintained by the board office. Notice that the president of the board has been notified and that s/he has given approval for an administrative fact-finding meeting shall be entered into the record;

(E) A format during the fact-finding meeting will be followed that allows the licensee to provide a statement of his/her own as well as a question/answer period allowed to discuss the aspects of the case centering on the chemical impairment issues or on any related concerns about the individual's ability to practice pharmacy;

(F) After the fact-finding meeting is concluded, a summary will be provided to each member of the board within the appropriate agenda, along with recommendations from the director as to any action to be taken. In addition, the president will be contacted and provided any follow-up information that could warrant changes in administrative procedures. The president, by executive order, may initiate an affidavit to the board attorney of an intent to file a complaint with the Administrative Hearing Commission. Once an order is executed, the information on the case shall be forwarded to the attorney for necessary legal preparation; and

(G) The entire board shall consider the case in closed session as to whether or not to file a complaint against the licensee and consider the recommendations made as to terms. Once the board authorizes a complaint, the attorney for the board shall assure that the appropriate filings take place.

(6) When an impaired pharmacist is disciplined by the board and a term of the discipline is that s/he participate in a chemical dependence treatment program, the impaired pharmacist shall select a program which meets the following guidelines:

(A) Persons who are involved in the treatment or counseling of a Missouri board-licensed pharmacist must submit written documentation of their credentials and qualifications to provide treatment or counseling;

(B) A written agreement or contract must be provided and executed between the counselor(s) and the licensee, outlining the responsibilities of each party for a successful treatment and monitoring program. The agreement must include a provision for sharing information concerning all aspects of therapy between the treatment facility or counselors, or both, and the Missouri Board of Pharmacy;

(C) An initial evaluation report must be completed and provided to the board outlining the licensee's present state of impairment, the recommended course(s) of treatment, the beginning date of treatment and an assessment of future prospects for recovery;

(D) A copy of the proposed treatment plan must be provided to the board and must include a provision outlining the method of referral to an appropriate after-care program;

(E) The counselor(s) must provide progress reports to the board as follows:

1. Inpatient therapy – monthly reports;

2. Outpatient therapy – quarterly reports; and
3. After-care programs – semiannual reports;

(F) The treatment program must include randomized and witnessed body fluid testing and analysis, with any drug presence not supported by a valid prescription to be reported to the Missouri Board of Pharmacy;

(G) The treatment program must include a provision for reporting any violation of the treatment contract or agreement by the licensee to the board; and

(H) All reports outlined in this protocol must be provided in writing to the board for a counselor or treatment facility, or both, to be approved for the treatment of a licensee undergoing disciplinary board action.

AUTHORITY: sections 338.140, RSMo Supp. 1989 and 338.240, RSMo 1986. This rule originally filed as 4 CSR 220-2.170. Original rule filed Oct. 1, 1987, effective Jan. 14, 1988. Amended: Filed Nov. 15, 1988, effective March 11, 1989. Moved to 20 CSR 2220-2.170, effective Aug. 28, 2006.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989 and 338.240, RSMo 1951.*

20 CSR 2220-2.175 Well-Being Program

PURPOSE: This rule establishes guidelines for the operation of the Well-Being Committee, pursuant to section 338.380, RSMo.

(1) Definitions.

(A) Board – State Board of Pharmacy.

(B) Impairment – An illness, substance abuse, or physical or mental condition suffered by a licensee that is reasonably related to the ability to practice pharmacy.

(C) Licensee – Pharmacist, intern pharmacist, or technician licensed or registered in the state of Missouri or who has applied for licensure or registration in the state of Missouri.

(D) Well-Being Committee – The committee established pursuant to section 338.380, RSMo, authorized to create, operate, and maintain the Well-Being Program.

(E) Well-Being Program – The program operated by the Well-Being Committee for purposes of early identification, intervention, treatment, and rehabilitation of pharmacists, intern pharmacists, and pharmacy technicians who may be impaired by reasons of illness, substance abuse, or as a result of any physical or mental condition.

(2) The board may contract with a contractor for purposes of creating and operating the Well-Being Program. Operational costs of the Well-Being Program may be paid by the board, subject to available funding. All costs of drug screens and professional and administrative services provided to a participant shall be paid by the participant, unless otherwise provided by the board.

(3) A participant may enter the Well-Being Program voluntarily or by referral of the board pursuant to a settlement agreement or other disciplinary order. Participants entering the Well-Being Program voluntarily shall be subject to and comply with all requirements of this rule. Each participant shall be financially responsible for all drug screens and any other professional or administrative service rendered on behalf of the participant.

(4) Well-Being Committee Duties.

(A) The committee shall oversee all aspects of the Well-Being Program including, but not limited to, program administration, staffing, financial operations, and case management. The committee shall provide services as needed to carry out the functions of section 338.380, RSMo, including, but not limited to:

1. Referring participants for appropriate assessment or evaluation and ensuring that treatment recommendations based on the assessment are followed as deemed appropriate by the board or committee;
2. Assisting the participant in obtaining evaluation and treatment;
3. Monitoring participant compliance with the contract between the committee and participant;
4. Monitoring the participant's compliance with the terms of any board disciplinary order/agreement;
5. Monitoring treatment progress and re-entry contractual compliance;
6. Managing/monitoring random drug screens;
7. Assisting participants to re-enter practice from treatment;
8. Assisting with aftercare issues or recommendations;
9. Program development;
10. Outreach education, as requested by the board by contract;
11. Managing, ensuring, and monitoring random and scheduled drug screens; and
12. Other necessary services as agreed by the board and committee.

(B) The committee shall enter into written contracts with each participant. Unless otherwise approved by the board, the contract between the committee and the participant shall be a minimum of five (5) years or the time designated by the board, and shall include, but shall not be limited to, the following conditions/requirements:

1. Each participant shall comply with all terms, conditions, or treatment identified, required, or recommended by the committee or the board for the treatment, evaluation, monitoring, or assessment of the participant;
2. Each participant shall abstain from the possession or consumption of legend medication, except as prescribed by a treating prescriber or approved by the committee;
3. Each participant shall abstain from possession and the consumption of alcohol, and the possession or consumption of illegal drugs;
4. Each participant shall submit to random drug testing unless otherwise specified by the board or committee;
5. Each participant shall enter treatment within forty-eight (48) hours following the committee's or an approved evaluator's determination that the participant needs treatment, unless otherwise approved by the board or committee;
6. Each participant shall report to the committee all relapses or other breaches of the contractual terms;
7. Each participant shall report to or meet with the board or committee, or a board or committee appointed designee, as may be requested by the board/committee;
8. Each participant shall attend support meetings as requested by the committee or treatment providers;
9. Each participant referred to the Well-Being Program by the board shall authorize the committee to release any and all information regarding the participant to the board;
10. Each participant voluntarily enrolled in the Well-Being Program shall authorize the committee to release any and all information or documents regarding the participant to the board upon a violation of any state or federal drug law or if the participant breaches or fails to comply with any terms of a Well-Being contract; and

11. Each participant shall be financially responsible for all drug screens and any other professional or administrative service rendered on behalf of the participant.

(5) Committee Administrator Duties.

(A) The Well-Being Committee shall appoint and designate a committee administrator for approval by the board. The committee administrator shall oversee and manage the daily operations of the committee and assist with committee administrative duties.

(B) The committee administrator shall possess a combination of education and experience in the area of addiction counseling and be currently licensed in Missouri as a psychologist, psychiatrist, professional counselor, or clinical social worker. Upon request of the committee, the board may waive the licensure requirements of this subsection for qualified applicants that otherwise possess an equivalent combination of education and experience, as required by this rule.

(C) The committee administrator shall also be familiar with licensees suffering from impairment issues which include, but shall not be limited to, the following:

1. Dependency;
2. Alcohol addiction;
3. Drug addiction;
4. Other addictive diseases;
5. Physical issues; and
6. Mental health issues.

(6) Voluntary Participants.

(A) Except as otherwise provided in this subsection, the identity of participants who voluntarily submit to the Well-Being Program shall remain anonymous to the board.

(B) The contractor shall file a Notice of Non-Compliance with the board against any voluntary participant who breaches or fails to comply with the terms of any Well-Being Program contract or who violates any state or federal drug law. The Notice of Non-Compliance must include the participant's name, license number, and the factual basis for the alleged contractual breach/non-compliance. The committee shall also supply to the board any information or documentation that supports or evidences the alleged non-compliance.

(7) Reporting.

(A) The committee shall provide to the board in writing –

1. An annual action plan and budget as directed by the board. The committee shall report on progress with regard to preparing and implementing the action plan and budget as requested by the board;

2. Progress reports with regard to each participant in or being assisted by the Well-Being Program, provided the identity of participants who voluntarily submit to the Well-Being Program shall remain anonymous to the board for purposes of these reports, except as otherwise provided by this rule;

3. Participant treatment, evaluation, and rehabilitation records as requested by the board, except as otherwise provided by this rule;

4. Quarterly income and expense reports for the Well-Being Program or other financial report requested by the board regarding the operation of the Well-Being Program; and

5. Any other report or information requested by the board, except as otherwise provided by this rule for voluntary participants.

(B) Violation reporting. In addition to the other requirements of this rule, the committee shall report to the board in writing –

1. All participant violations of a board disciplinary order/agreement, any provision of Chapter 338, RSMo, or the board regulations, or any state or federal drug law, which occurs after the date of the disciplinary order/agreement or the date the participant entered the Well-Being Program, whichever occurs first;

2. Any participant who fails to enter treatment within forty-eight (48) hours following the committee's or an evaluator's determination that the participant needs treatment;

3. Any participant who does not comply with the terms of a Well-Being Program contract or who resumes the practice of pharmacy before an approved treatment provider or committee has made a clear determination that the licensee is capable of practicing; and

4. Any breach of contract by the Well-Being Committee or committee administrator.

(8) Confidentiality.

(A) Except as otherwise provided by this rule, the committee shall provide the board access to all information pertaining to each participant referred to the committee by the board.

(B) The board and committee may exchange privileged and confidential information, interviews, reports, statements, memoranda, and other documents including information on investigations, findings, conclusions, interventions, treatment, rehabilitation, and other proceedings of the board and committee, and other information closed to the public, as needed to effectuate section 338.380, RSMo, or to promote the identification, intervention, treatment, rehabilitation, and discipline (accountability) of participants who may be impaired.

(C) All privileged and confidential information and other information not considered to be public records or information pursuant to Chapter 610, RSMo, shall remain privileged and confidential and closed to the public after such information is exchanged.

AUTHORITY: section 338.140.1, RSMo Supp. 2022, and section 338.380, RSMo 2016. Original rule filed Aug. 18, 2009, effective March 30, 2010. Amended: Filed Jan. 6, 2023, effective July 30, 2023.*

**Original authority: 338.140.1, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019, and 338.380, RSMo 2007.*

20 CSR 2220-2.180 Public Records

PURPOSE: This rule establishes standards for compliance with Chapter 610, RSMo as it relates to public records of the State Board of Pharmacy.

(1) All public records of the State Board of Pharmacy will be open for inspection and copying by any member of the general public during normal business hours, holidays excepted, except for those records closed pursuant to section 610.021, RSMo. All public meetings of the Board of Pharmacy not closed pursuant to the provisions of section 610.021, RSMo will be open to any member of the public.

(2) The Board of Pharmacy establishes the executive director of the board as the custodian of its records as required by section 610.023, RSMo. The executive director is responsible for the maintenance of the board's records and is responsible for responding to requests for access to public records.

(3) When a request for inspection of public records is made and

the individual inspecting the records requests copies of the records, the board will collect the appropriate fee for costs for inspecting and copying of the records, as outlined in the board's fee rule, 20 CSR 2220-4.100. The board may require payment of the fees prior to making available any public records.

(4) Written requests for access to records and responses to the requests will be maintained by the board as a public record for two (2) years. Such records will be open for inspection by any member of the general public during regular business hours, as required by state law.

AUTHORITY: sections 338.140 and 338.280, RSMo 2016, and Chapters 610 and 620, RSMo 2016 and Supp 2019. This rule originally filed as 4 CSR 220-2.180. Original rule filed Jan. 19, 1988, effective April 28, 1988. Amended: Filed June 26, 1995, effective Feb. 25, 1996. Moved to 20 CSR 2220-2.180, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Dec. 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989 and 338.280, RSMo 1951, amended 1971, 1981. For Chapters 610 and 620, please consult the Missouri Revised Statutes.*

20 CSR 2220-2.190 Patient Counseling

PURPOSE: This rule establishes minimum standards for patient counseling to comply with the federal Omnibus Budget Reconciliation Act of 1990 which requires that all states establish standards by January 1, 1993.

(1) Upon receipt of a prescription drug order and following a review of the available patient information, a pharmacist or his/her designee shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of each patient. Counseling shall be conducted by the pharmacist or a pharmacy extern under the pharmacist's immediate supervision to allow the patient to safely and appropriately utilize the medication so that maximum therapeutic outcomes can be obtained. If the patient or caregiver is not available, then a written offer to counsel with a telephone number of the dispensing pharmacy at no cost to the patient must be supplied with the medication so that the patient or caregiver may contact the pharmacist for counseling when necessary. In situations where automated pick-up systems are used for providing refill prescriptions to patients, the offer to counsel may be provided within the information provided by the kiosk to the patient during the processing phase prior to release of the medication to the patient. The elements of counseling shall include matters which the pharmacist deems significant in the exercise of his/her professional judgment and is consistent with applicable state laws.

(2) Pharmacies shall maintain appropriate patient information to facilitate counseling. This may include, but shall not be limited to, the patient's name, address, telephone number, age, gender, clinical information, disease states, allergies and a listing of other drugs prescribed.

(3) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples may include, but shall not be limited to, written information leaflets, pictogram labels, video programs, and the like.

(4) Patient counseling, as described in this rule, shall not be required for inpatients of a hospital, institution or other setting where other licensed or certified health care professionals are authorized to administer medications.

(5) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses consultation.

AUTHORITY: sections 338.140 and 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.190. Original rule filed May 1, 1992, effective Feb. 26, 1993. Amended: Filed March 4, 1993, effective Oct. 10, 1993. Moved to 20 CSR 2220-2.190, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.195 Prospective Drug Utilization Review

PURPOSE: This rule establishes requirements for prospective drug utilization review prior to dispensing a prescription or medication order.

(1) Prospective Drug Review.

(A) Prior to dispensing or otherwise approving medication for patient use, pharmacists shall use their professional judgment to review available patient records to assess therapeutic appropriateness.

(B) The pharmacist shall take appropriate steps within their professional judgment to address or resolve identified therapeutic appropriateness issues. Prospective drug review may only be performed by a pharmacist or an intern pharmacist working under the supervision of a Missouri licensed pharmacist.

AUTHORITY: sections 338.100 and 338.280, RSMo 2016, and sections 338.035 and 338.140, RSMo Supp. 2020. Original rule filed Sept. 1, 2020, effective Feb. 28, 2021.*

**Original authority: 338.035, RSMo 1990, amended 1993, 1995, 2007, 2020; 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010, 2016; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.200 Sterile Compounding

PURPOSE: This rule establishes standards for the handling, labeling, distribution, and dispensing of compounded sterile preparations by licensed pharmacies, pursuant to a physician's order or prescription.

PUBLISHER'S NOTE: The secretary of state has determined that publication of the entire text of the material that is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Definitions.

(A) Aseptic processing: The technique involving procedures designed to preclude contamination of drugs, packaging, equipment, or supplies by microorganisms during processing.

(B) Batch: Compounding of multiple sterile preparation units in a single discrete process, by the same individuals, carried out during one (1) limited time period.

(C) Beyond-Use date: A date after which a compounded preparation should not be used and is determined from the date the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their beyond-use dates must be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products.

(D) Biological safety cabinet: Containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the preparation, personnel, and environment, according to National Sanitation Foundation (NSF) International standards.

(E) Buffer area: An ISO Class 7 or better area where the primary engineering control is physically located that is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room and in which other relevant variables (e.g., temperature, humidity, and pressure) are controlled as necessary.

(F) Compounding: For the purposes of this regulation, compounding is defined as in 20 CSR 2220-2.400(1). Compounded sterile medications may include, but are not limited to:

1. Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that must or are required to be sterile when they are administered to patients, including, but not limited to, the following dosage forms: bronchial and inhaled nasal preparations intended for deposition in the lung(s), baths and soaks for live organs and tissues, epidural and intrathecal solutions, bladder/wound solutions, injectables, implantable devices and dosage forms, inhalation solutions, intravenous solutions, irrigation solutions, ophthalmic preparations, parenteral nutrition solutions, and repackaged sterile preparations. Nasal sprays and irrigations intended for deposit in the nasal passages may be prepared as nonsterile compounds;

2. An FDA approved manufactured sterile product that is either prepared according to the manufacturers' approved labeling/recommendations or prepared differently than published in such labeling; and

3. Assembling point-of-care assembled systems.

(G) Compounding aseptic containment isolator (CACI): A restricted access barrier system (RABS) that is designed for compounding sterile hazardous drugs and designed to provide worker protection from exposure to undesirable levels of airborne drugs throughout the compounding and material transfer processes and to provide an aseptic environment for Compounded Sterile Preparation (CSPs).

(H) Compounding aseptic isolator (CAI): A RABS specifically designed for compounding sterile non-hazardous pharmaceutical ingredients or CSPs and designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes.

(I) Controlled area: For purposes of these regulations, a controlled area is a separate room designated for preparing sterile preparations or an area designated for preparing sterile preparations that is separated from other activities/operations by a line of demarcation that clearly separates the area from other operations.

(J) Critical area: Any area in the controlled area where preparations or containers are exposed to the environment.

(K) Critical site: Any surface, pathway, or opening (e.g., vial septa, injection ports, beakers, needle hubs) that provides a direct pathway between a compounded sterile preparation or other ingredient used to compound a sterile preparation and the air, environment or moisture, or that poses a risk of touch contamination.

(L) CSP: Compounded sterile preparation.

(M) Cytotoxic drugs: A pharmaceutical product that has the capability of direct toxic action on living tissue that can result in severe leukopenia and thrombocytopenia, depression of the immune system, and the alteration of a host's inflammatory response system.

(N) Emergency dispensing: Is a situation where a Risk Level 3 preparation is necessary for immediate administration of the preparation and no alternative product or preparation is available and the prescriber is informed that the preparation is being dispensed prior to appropriate testing. Documentation of the dispensing of the preparation, the prescriber's approval for dispensing prior to the receipt of test results and the need for the emergency must appear within the prescription record. A separate authorization from the prescriber is required for each emergency dispensing.

(O) High-Efficiency Particulate Air (HEPA) filter: A filter composed of pleats of filter medium separated by rigid sheets of corrugated paper or aluminum foil that direct the flow of air forced through the filter in a uniform parallel flow. HEPA filters remove ninety-nine point ninety-seven percent (99.97%) of all particles three-tenths (0.3) microns or larger. When HEPA filters are used as a component of a horizontal- or vertical-laminar-airflow workbench, an environment can be created consistent with standards for an ISO Class 5 environment.

(P) In-use time/date: The time/date before which a conventionally manufactured product or a CSP must be used after it has been opened or needle-punctured.

(Q) ISO Class 5: An area with less than three thousand five hundred twenty (3,520) particles (0.5 µm and larger in size) per cubic meter.

(R) ISO Class 7: An area with less than three hundred fifty-two thousand (352,000) particles (0.5 µm and larger in size) per cubic meter.

(S) Multiple-dose container: A multiple unit container for articles or compounded sterile preparations that contains more than one (1) dose of medication and usually contains an antimicrobial preservative.

(T) Parenteral: A sterile preparation of drugs for injection through one (1) or more layers of skin.

(U) Point-of-care assembled system: A closed system device that creates a physical barrier between diluents, fluids, or other drug components and is designed to be activated by the end user by allowing the components to mix prior to administration.

(V) Primary engineering control (PEC): A system that provides an ISO 5 environment for the exposure of critical sites when compounding sterile preparations. PECs include, but may not be limited to, horizontal/vertical laminar airflow hoods, biological safety cabinets, and a RABS such as compounding aseptic isolators (CAIs), or compounding aseptic containment isolators (CACIs).

(W) Process validation or simulation: Microbiological simulation of an aseptic process with growth medium processed in a manner similar to the processing of the preparation and with the same container or closure system.

(X) Quality assurance: For purposes of these regulations, quality assurance is the set of activities used to ensure that the processes used in the preparation of sterile drug preparations lead to preparations that meet predetermined standards of quality.

(Y) Quality control: For the purposes of these regulations, quality control is the set of testing activities used to determine that the ingredients, components, and final sterile preparations prepared meet predetermined requirements with respect to

identity, purity, nonpyrogenicity, and sterility.

(Z) Restricted access barrier system (RABS): A primary engineering control that is comprised of a closed system made up of four (4) solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with coving between wall junctures. The air-handling system provides HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are designed to minimize the entry of contamination. Manipulations can take place through either glove ports or half suits. Examples of a RABS may include, but is not limited to, a CAI or CACI.

(AA) Repackaging: The subdivision or transfer of a compounded preparation from one (1) container or device to a different container or device.

(BB) Single-dose/single-unit container/vial: A container/vial of medication intended for administration that is meant for use in a single patient for a single case, procedure, or injection.

(CC) Sterilization: A validated process used to render a preparation free of viable organisms.

(DD) Temperatures:

1. Frozen means temperatures between twenty-five degrees below zero and ten degrees below zero Celsius (-25 and -10°C) (thirteen degrees below zero and fourteen degrees Fahrenheit (-13 and 14°F));

2. Refrigerated means temperatures between two and eight degrees Celsius (2 and 8°C) (thirty-six and forty-six degrees Fahrenheit (36 and 46°F)); and

3. Controlled room temperature means a temperature maintained thermostatically that encompasses the usual and customary working environment 20° to 25° Celsius (68° to 78° F). Excursions between 15° and 30° Celsius (59° to 86° F) as commonly experienced in pharmacies and other facilities shall be deemed compliant.

(EE) USP: *The United States Pharmacopeia and the National Formulary* (USP-NF) as adopted and published by the United States Pharmacopeial Convention, effective May 2013. Copies of the USP-NF are published by, and available from, USP, 12601 Twinbrook Parkway, Rockville, MD 20852-1790 or online at http://www.usp.org/. The USP-NF is incorporated herein by reference. This rule does not include any later amendments or additions to the USP-NF.

(FF) Validation: Documented evidence providing a high degree of assurance that specific processes will consistently produce a preparation meeting predetermined specifications and quality attributes.

(GG) Definitions of sterile compounded preparations by risk level:

1. Risk Level 1: Applies to compounded sterile preparations that exhibit characteristics A., B., or C., stated below. All Risk Level 1 preparations shall be prepared with sterile equipment and sterile ingredients and solutions in an ISO Class 5 environment. Risk Level 1 includes the following:

A. Preparations:

(I) Stored at controlled room temperature and assigned a beyond-use date of forty-eight (48) hours or less; or

(II) Stored under refrigeration and assigned a beyond-use date of seven (7) days or less; or

(III) Stored frozen and assigned a beyond-use date of thirty (30) days or less;

B. Unpreserved sterile preparations prepared for administration to one (1) patient or batch-prepared preparations containing suitable preservatives prepared for administration to more than one (1) patient with an assigned beyond-use date that does not exceed the beyond-use date allowed under subparagraph (1)(GG)1.A. of this rule;

C. Preparations prepared by closed-system aseptic transfer of sterile, nonpyrogenic, finished pharmaceuticals (e.g., from vials or ampules) obtained from licensed manufacturers into sterile final containers obtained from licensed manufacturers with an assigned beyond-use date that does not exceed the beyond-use date allowed under subparagraph (1)(GG)1.A. of this rule;

2. Risk Level 2: Sterile preparations exhibit characteristic A., B., or C., stated below. All Risk Level 2 preparations shall be prepared with sterile equipment and sterile ingredients in an ISO Class 5 environment and with closed-system transfer methods. Risk Level 2 includes the following:

A. Preparations stored under refrigeration and assigned a beyond-use date greater than seven (7) days, or preparations stored frozen and assigned a beyond-use date greater than thirty (30) days, or preparations stored at controlled room temperature and assigned a beyond-use date greater than forty-eight (48) hours;

B. Batch-prepared preparations without preservatives that are intended for use by more than one (1) patient;

C. Preparations compounded by complex or numerous manipulations of sterile ingredients obtained from licensed manufacturers in a sterile container or reservoir obtained from a licensed manufacturer by using closed-system aseptic transfer (e.g., automated compounder);

3. Risk Level 3: Sterile preparations exhibit either characteristic A. or B.:

A. Preparations compounded from nonsterile ingredients or compounded with nonsterile components, containers, or equipment before terminal sterilization;

B. Preparations prepared by combining multiple ingredients (sterile or nonsterile) by using an open-system transfer or open reservoir before terminal sterilization.

(2) Policy and Procedure Manual/Reference Manuals.

(A) A manual, outlining policies and procedures encompassing all aspects of Risk Level 1, 2, and 3 compounding performed, shall be available for inspection at the pharmacy. The manual shall be reviewed on an annual basis. The pharmacy shall have current reference materials related to sterile preparations.

(3) Personnel Education, Training, and Evaluation.

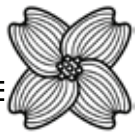
(A) Risk Level 1: All pharmacy personnel preparing sterile preparations must receive suitable didactic and experiential training in aseptic technique and procedures and shall be skilled and trained to accurately and competently perform the duties assigned. Additional training must be provided if the risk level of sterile activity conducted by the individual changes or if there is a change in compounding methods performed. To ensure competency, individuals preparing sterile preparations must successfully pass an Aseptic Technique Skill Assessment that complies with section (10) of this rule. The pharmacy shall establish policies and procedures for staff training and assessment.

(B) Risk Level 2: In addition to Risk Level 1 requirements, personnel training must include assessment of competency in all Risk Level 2 procedures via process simulation.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, operators have specific education, training, and experience to prepare Risk Level 3 preparations. The pharmacist knows principles of good compounding practice for risk level preparations, including –

1. Aseptic processing;

2. Quality assurance of environmental, component, and



end-preparation testing;
3. Sterilization; and
4. Selection and use of containers, equipment, and closures.

(4) Storage and Handling in the Pharmacy.

(A) Risk Level 1 and 2: Solutions, drugs, supplies, and compounding equipment must be stored and maintained in a manner that will maintain the chemical and microbiological stability of CSPs. Refrigeration, freezer and, if applicable, incubator temperatures shall be documented daily. Other storage areas shall be inspected regularly to ensure that temperature and lighting meet requirements. Drugs and supplies shall be shelved above the floor. Removal of drugs and supplies from boxes shall be done outside the controlled and buffer areas. Removal of used supplies from the controlled area shall be done at least daily. Preparation recall procedures must comply with section (21) of this rule and must permit retrieving affected preparations from specific involved patients.

(B) Risk Level 3: In addition to Risk Level 1 and 2 requirements, the pharmacy must establish procedures for procurement, identification, storage, handling, testing, and recall of components and finished preparations. Finished Risk Level 3 preparations awaiting test results must be quarantined under minimal risk for contamination in a manner that will maintain chemical and microbiological stability.

(5) Facilities and Equipment. The pharmacy shall establish and follow proper controls to ensure environmental quality, prevent environmental contamination, and maintain air quality in all ISO classified areas.

(A) Risk Level 1: Risk Level 1 preparations must be prepared in a PEC located in a controlled area that meets the requirements of this rule. A sink with hot and cold water must be near, but not in, the controlled area. The controlled area and inside equipment must be cleaned and disinfected as provided in section (17) of this rule. Activities within the critical area shall be kept to a minimum to maintain the ISO classified environment. Primary engineering controls shall meet the requirements of section (6) of this rule; prefilters must be visually inspected on a regularly scheduled basis and replaced according to manufacturer's specifications. Pumps utilized in the compounding process shall be recalibrated and documented according to manufacturer procedures.

(B) Risk Level 2: In addition to all Risk Level 1 requirements, Risk Level 2 preparations must be prepared in a PEC located in a buffer area or prepared in a RABS located within a controlled area. Applicable environmental monitoring of air and surfaces must be conducted. Risk Level 2 preparations shall at a minimum remain a Risk Level 2 for the life of the preparation.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, Risk Level 3 preparations must be prepared in a PEC located in a buffer area or prepared in a RABS located within a controlled area. All non-sterile equipment that is to come in contact with the sterilized final preparation must be sterilized before introduction in the buffer area or into the RABS.

(D) Automated compounding devices shall be calibrated according to manufacturer procedures for content, volume, weight, and accuracy prior to initial use and prior to compounding each day the device is in use or more frequently as recommended by manufacturer guidelines. Calibration results shall be reviewed by a pharmacist to ensure compliance. The identity of the reviewing pharmacist and the review date shall be documented in the pharmacy's records.

(E) All PECs and ISO classified areas shall be certified to ensure compliance with the requirements of this rule prior to beginning sterile compounding activities and every six (6) months thereafter. Certification shall be conducted by competent staff/vendors using recognized and appropriate certification and testing equipment. Certification results shall be reviewed by a pharmacist once received. The pharmacist's identity and date of review must be documented in the pharmacy's records. Deficiencies or failures shall be investigated and corrected prior to further compounding which may include recertification of the PEC/ISO classified area.

1. The PEC and ISO classified areas must be recertified when – 1) any changes or major service occurs that may affect airflow or environmental conditions or 2) the PEC or room is relocated or the physical structure of the ISO classified area has been altered.

2. Corrections may include, but are not limited to, changes in the use of the affected PEC or ISO classified area or initiating a recall.

(F) Pressure differential: If the sterile compounding area is equipped with a device to monitor pressure differential between ISO classified air spaces, pressure differential results must be recorded and documented each day that the pharmacy is open for pharmacy activities. Alternatively, a continuous monitoring system may be used to record pressure differential results if the system maintains ongoing documentation of pressure recordings or maintains pressure alerts that are reviewed daily.

(6) Primary Engineering Controls (PECs).

(A) PECs must be properly used, operated, and maintained and must be located out of traffic patterns and away from conditions that could adversely affect their operation or disrupt intended airflow patterns (e.g., ventilation systems or cross-drafts).

(B) PECs shall maintain ISO Class 5 or better conditions during dynamic operating conditions and while compounding sterile preparations, including, when transferring ingredients into and out of the PEC and during exposure of critical sites.

(C) PECs shall provide unidirectional (laminar flow) HEPA air at a velocity sufficient to prevent airborne particles from contacting critical sites.

(D) The recovery time to achieve ISO Class 5 air quality in any PEC shall be identified in the pharmacy's policies and procedures. Procedures must be developed to ensure adequate recovery time is allowed before or during compounding operations and after material transfer.

(7) Controlled Areas. The controlled area shall be designed, maintained, and controlled to allow effective cleaning and disinfection and to minimize the risk of contamination and the introduction, generation, and retention of particles inside the PEC.

(A) Controlled areas must be clean and well-lit and shall be free of insects, rodents, and/or other vermin. Trash shall be disposed of in a timely and sanitary manner and at least daily. Tacky mats or similar articles are prohibited in the controlled area or any ISO classified environment.

(B) Traffic flow in or around the controlled area shall be minimized and controlled. Food items, chewing gum, eating, drinking, and smoking are prohibited in the area.

(C) Non-essential objects that shed particles shall not be brought into the controlled area, including, but not limited to, pencils, cardboard cartons, paper towels, and cotton items (e.g., gauze pads). Furniture, carts, supplies, and equipment shall be removed from shipping cartons/containers and properly cleaned and disinfected with sterile alcohol or an equivalently

effective non-residue generating disinfectant before entering any ISO classified area. No shipping or other external cartons may be taken into the controlled area or an ISO classified area.

(D) Only supplies essential for compounding shall be stored in the controlled area. Supplies or other non-essential equipment shall not be stored in or on the PEC.

(8) Garbing and Hand Hygiene. Individuals engaged in, or assisting with, CSPs shall be trained and demonstrate competence in proper personal garbing, gloving, and hand hygiene. Competence must be documented and assessed through direct visual observation as part of the aseptic technique skill assessment required by this rule.

(A) Risk Level 1: Low-particulate and non-shedding gowns, hair covers, gloves, face masks, and, if applicable, beard covers must be worn during compounding and cleaning. All head and facial hair must be covered. During sterile preparation, gloves shall be disinfected before use and frequently thereafter with a suitable agent and changed when integrity is compromised. All personnel in the controlled area must be appropriately garbed as required by this section.

(B) Risk Level 2 and Risk Level 3: In addition to Risk Level 1 requirements, shoe covers and sterile gloves must be worn while compounding and cleaning, including, over RABS gloves. All personnel in the controlled or buffer area must garb as required by this section.

(9) Aseptic Technique and Preparation. Appropriate quality control methods shall be maintained over compounding methods at all times to ensure proper aseptic technique.

(A) Risk Level 1: Sterile preparations must be prepared in an ISO Class 5 environment. Personnel shall scrub their hands and forearms a minimum of thirty (30) seconds and remove debris from underneath fingernails under warm running water before donning the required gloves. Eating, drinking, and smoking are prohibited in the controlled area. Talking shall be minimized to reduce airborne particles. Ingredients shall be determined to be stable, compatible, and appropriate for the preparation to be prepared, according to manufacturer, USP, or scientific references. Ingredients and containers shall be inspected for defects, expiration, and integrity before use. Only materials essential for aseptic compounding shall be placed in the PEC. Supplies, equipment, and the surfaces of ampules and vials shall be disinfected before entering the PEC by wiping the outer surface with sterile alcohol or an equivalently effective non-residue generating disinfectant. Sterile components shall be arranged in the PEC to allow a clear, uninterrupted path of HEPA-filtered air over critical sites. Automated devices and equipment shall be cleaned, disinfected, and placed in the PEC to enable laminar airflow. Aseptic technique shall be used to avoid touch contamination of critical sites of containers and ingredients. Particles shall be filtered from solutions, if applicable. Needle cores shall be avoided. The pharmacist shall check before, during, and after preparation to verify the identity and amount of ingredients before release.

(B) Risk Level 2: In addition to Risk Level 1 requirements, a file containing the formula, components, procedures, sample label, and final evaluation shall be made for each preparation batch. A separate work sheet and lot number for each batch shall be completed. When combining multiple sterile preparations, a second verification of calculations shall take place. The pharmacist shall verify data entered into any automatic compounder before processing and check the end preparation for accuracy.

(C) Risk Level 3: In addition to Risk Level 1 and 2 requirements, nonsterile components must meet compendial standards or must be verified by a pharmacist and a certificate of analysis. Batch preparation files shall also include comparisons of actual with anticipated yields, sterilization methods, and quarantine specifications. Presterilized containers shall be used when feasible. Final containers must be sterile and capable of maintaining preparation integrity throughout the shelf life. Sterilization methods must be based on properties of the preparation, and must be conducted in a method recognized by USP for the preparation and confirmed through sterility testing using a testing method recognized by USP for the preparation.

(D) Single-dose vials/containers and pharmacy bulk vial/containers exposed to ISO Class 5 or cleaner air may be used in compounding until the assigned in-use time which shall not exceed six (6) hours after initial needle puncture, unless otherwise specified by the manufacturer. Opened single-dose ampules shall not be stored for any time period. The in-use time must be placed on the vial/container. For multiple-dose vials/containers with no antimicrobial preservative used in the preparation of radiopharmaceuticals whose beyond-use dates are twenty-four (24) hours or less, the in-use time shall not exceed twenty-four (24) hours.

(E) Unless otherwise specified by the manufacturer, multiple-dose vials/containers with an antimicrobial preservative may be used in compounding until the assigned in-use date which shall not exceed twenty-eight (28) days after initially entering or opening the vial/container (e.g., needle-puncture). The in-use date must be placed on the vial/container.

(10) Aseptic Technique Skill Assessment. Individuals engaged in sterile compounding must take and successfully pass an aseptic technique skill assessment to verify aseptic competency. The assessment must include a direct visual observation of the individual's aseptic competency during a process simulation that represents the most challenging or stressful conditions encountered or performed by the person being evaluated. The assessment must include media-fill testing for all risk levels performed. Self-observation is not allowed.

(A) The required visual observation shall assess:

1. Proper aseptic technique, manipulations, and work practices, including, but not limited to, avoiding touch contamination, proper use of first air, and if applicable, sterilizing high risk CSPs;
2. Cleaning and disinfection;
3. Hand hygiene, gloving, and garbing;
4. Identifying, weighing, and measuring of ingredients;
5. Maintaining sterility in ISO Class 5 areas;
6. Labeling and inspecting CSPs for quality.

(B) Media-Fill Testing. Pharmacies shall establish and follow policies and procedures for media-fill testing. Media-fill testing shall comply with USP Chapter 797's recommended procedures and methods and must be conducted using the most challenging or stressful conditions/compounding actually encountered or performed by the person being evaluated using the same container or closure. A minimum of three (3) media-fill tests must be completed during initial media-fill testing and one (1) media-fill test completed for ongoing testing.

(C) Frequency: The required Aseptic Technique Skill Assessment must be conducted prior to initial compounding and every twelve (12) months thereafter for Risk Levels 1 and 2 compounding and every (6) months thereafter for Risk Level 3 compounding. Additionally, an Aseptic Technique Skill Assessment must be conducted whenever unacceptable techniques are observed or discovered, if the risk level of sterile

activity conducted by the individual changes, or if there is a change in compounding methods performed.

(D) Individuals who fail written tests; visual observation of hand hygiene, garbing, or aseptic technique; or media-fill tests must undergo immediate requalification through additional training by competent compounding personnel. Individuals who fail visual observation of hand hygiene, garbing, or aseptic technique; or media-fill tests must pass a reevaluation in the deficient area before they can resume compounding of sterile preparations. Individuals who fail media-fill testing must pass three (3) successive media-fill tests prior to resuming sterile compounding.

(E) If needed to prevent interruptions in patient care during an emergency, a pharmacy may accept aseptic technique skill assessment results from another pharmacy or hospital in lieu of the required initial aseptic technique skill assessment, provided –

1. A pharmacist verifies the aseptic technique skill assessment to be accepted complies with the requirements under subsections (10)(A)–(C) of this rule for an ongoing aseptic technique skill assessment, at a minimum;

2. The pharmacy maintains documentation of the other pharmacy or hospital's completed aseptic technique skill assessment, including the dates and results of the required training, visual observation, and media-fill testing. Additionally, the receiving pharmacy must maintain a manual or electronic copy of the other pharmacy's or hospital's policies and procedures on aseptic technique skill assessment and media-fill testing for board licensees or registrants;

3. The board licensee or registrant has received training on applicable pharmacy operational procedures as needed to ensure proper compounding. The licensee or registrant must be skilled and trained to accurately and competently perform the duties; and

4. Individuals may not assist with compounding under the emergency allowance authorized by this subsection for more than forty-five (45) days without an initial aseptic technique skill assessment for the pharmacy.

(11) Record Keeping.

(A) Risk Level 1 and 2: The following must be documented/maintained:

1. Training and competency evaluation of pharmacy personnel involved in sterile compounding, including, the dates and results of the required aseptic technique training, aseptic technique skill assessment, and media-fill testing;

2. Refrigerator, freezer and, if applicable, incubator temperature logs;

3. Certification dates and results for any PEC or ISO classified area;

4. Manufacturer manuals that are relied upon to maintain compliance with this rule;

5. Other facility quality control logs, as appropriate, including all maintenance, cleaning, and calibration records;

6. If applicable, pressure recordings including documentation of the review of continuous monitoring system results as required by subsection (5)(F);

7. Any end-preparation testing records; and

8. Single preparation and batch preparation records.

(B) Risk Level 3: In addition to Risk Level 1 and 2 requirements, record requirements for Risk Level 3 preparations must include:

1. Preparation work sheet;

2. Sterilization records;

3. Quarantine records, if applicable;

4. End-preparation evaluation and testing records as required in section (14); and

5. Ingredient validation records as required in section (14).

(C) All records and reports shall be maintained either electronically or physically for two (2) years and shall be readily retrievable and subject to inspection by the board of pharmacy or its agents. At a minimum, records shall be physically or electronically produced immediately or within two (2) hours of a request from the board or the board's authorized designee.

(12) Labeling.

(A) Sterile preparations shall be labeled in accordance with section 338.059, RSMo and with the following supplemental information:

1. Beyond-use date;

2. Storage requirements if stored at other than controlled room temperature;

3. Any device specific instructions;

4. Auxiliary labels, when applicable; and

5. If applicable, a designation indicating the preparation is hazardous.

(13) Beyond-Use Dating.

(A) Risk Level 1 and Risk Level 2: All sterile preparations must bear a beyond-use date. Beyond-use dates must be assigned based on current drug and microbiological stability information and sterility considerations.

(B) Risk Level 3: In addition to all Risk Level 1 requirements, there must be a reliable method for establishing all beyond-use dates, including laboratory testing of preparation stability, pyrogenicity, particulate contamination, and potency. Beyond-use dating not specifically referenced in the products approved labeling or not established by preparation specific instrumental analysis shall be limited to thirty (30) days. There must be a reliable method for establishing all beyond-use dating. Preparations assigned a beyond-use date of greater than thirty (30) days shall have laboratory validation of preparation stability and potency.

(14) End-preparation Evaluation.

(A) Risk Level 1: The final preparation must be inspected for clarity, container leaks, integrity, and appropriate solution cloudiness or phase separation, solution color, and solution volume. The pharmacist must verify that the preparation was compounded accurately as to the ingredients, quantities, containers, and reservoirs. Background light or other means for the visual inspection of preparations for any particulate and/or foreign matter must be used as part of the inspection process, provided an alternate means of inspection shall be used if a visual inspection or exposure to the preparation may pose a health hazard.

(B) Risk Level 2: All Risk Level 1 requirements must be met.

(C) Risk Level 3: In addition to all Risk Level 1 requirements, the process validation procedure shall be supplemented with a program of end-preparation sterility testing according to a formal sampling plan. Samples shall be statistically valid to ensure that batches are sterile. A method for recalling batch preparations shall be established if preparation testing results are unacceptable. A sample from each sterile preparation/batch must be tested for sterility. A sample from each parenteral sterile preparation/batch must also be tested for pyrogenicity. Risk Level 3 preparations must be quarantined and stored to maintain chemical and microbiological stability pending results of end-preparation testing.

1. Sterility testing: Sampling for the sterility test shall occur promptly upon the completion of preparation. The sterility test,

including the sampling scheme, shall be conducted according to a method recognized for the preparation by USP Chapter 71.

2. Pyrogen/Endotoxin testing: Sterile parenteral preparations prepared from non-sterile drug components shall be tested for pyrogen or endotoxin according to a method recognized by USP Chapter 151 for pyrogen testing and recognized by USP Chapter 85 for endotoxin testing.

3. Potency: The pharmacy shall have a procedure for a pre-release check of the potency of the active ingredients in the compounded sterile preparation prepared from non-sterile bulk active ingredients. The procedure shall include at least the following verifications by a pharmacist:

A. The lot of the active ingredients used for compounding have the necessary labeling, potency, purity, certificate of analysis, and other relevant qualities;

B. All weighings, volumetric measurements, and additions of ingredients were carried out properly;

C. The compounding or control records include documentation that the fill volumes of all units available for release were checked and were correct; and

D. The final potency is confirmed by instrumental analysis for sterile preparations that have been assigned a beyond-use date of more than thirty (30) days.

(D) Emergency Dispensing of a Risk Level 3 Sterile Preparation: When a compounded Risk Level 3 preparation must be released prior to the completion of testing, the sterile preparation may be dispensed pending test results. Emergency dispensing shall be defined as, and comply with, subsection (1)(N) of this rule.

(15) Storage, Handling, and Transport. Sterile preparations shall be packaged, stored, dispensed, and distributed in a manner that will maintain the preparation's chemical and microbiological stability until the assigned beyond-use date or until delivery to the patient or intended recipient. The pharmacist-in-charge shall assure the environmental control of all sterile compounded preparations shipped. Sterile preparations shall be transported so as to be protected from excesses of temperatures and light within appropriate packaging or delivery containers that maintain necessary storage conditions to preserve the quality and integrity of sterile preparations. The pharmacy shall follow written procedures that specify packing techniques, configuration, and materials for groups of preparations with common storage characteristics and for specific preparations where unique storage conditions are required to retain adequate stability and preparation quality.

(16) Point-of-Care Assembled Systems. Assembly of point-of-care assembled systems shall be considered Risk Level 1 compounding. Point-of-care assembled systems shall be assigned a beyond-use date which may exceed the beyond-use date authorized for Risk Level 1 preparations provided the date is assigned in accordance with the manufacturer's recommendations or labeling.

(A) When dispensed, an assembled non-activated system shall be labeled with beyond-use dates for both activated and non-activated states. The compounding record must document both dates. The beyond-use date of an assembled non-activated system shall be limited to a maximum of fifteen (15) days unless the pharmacy has documentation from the system's manufacturer that a longer date is acceptable.

(B) Point-of-care assembled systems shall be assembled and stored in accordance with the manufacturer's labeling and recommendations.

(17) General Cleaning and Disinfection Requirements. Except as otherwise provided herein, cleaning and disinfection of controlled and buffer areas, supplies, and equipment shall be performed and conducted in accordance with USP Chapter 797 timeframes and procedures. Controlled areas that do not meet ISO air classifications shall be cleaned and disinfected as required by USP Chapter 797 for segregated compounding areas. If compounding is done less frequently than the cleaning and disinfection timeframes specified in USP Chapter 797, cleaning and disinfection must occur before each compounding session begins.

(A) The pharmacy shall establish and follow written policies and procedures governing all aspects of cleaning and disinfection, including approved cleaning/disinfecting agents and materials, schedules of use, and methods of application.

(B) Individuals shall be trained in proper cleaning and disinfection procedures prior to performing such activities. Training shall include direct visual observation of the individual's cleaning and disinfecting process by qualified staff. The individual shall be annually reassessed for competency through direct visual observation. Documentation of the required training and training dates shall be maintained in the pharmacy's records. Individuals who fail to demonstrate competency shall be reinstructed and successfully reevaluated prior to any further cleaning or disinfection.

(C) Cleaning and disinfection activities shall be performed using approved cleaning/disinfection agents and procedures described in the pharmacy's written policies and procedures. Manufacturers' directions for minimum contact time shall be followed.

(D) All cleaning tools (e.g., wipes, sponges, and mop heads) must be low-lint and dedicated for use in the controlled area and ISO classified areas.

(E) Primary engineering controls shall be cleaned with a germicidal cleaning agent followed by sterile alcohol. Sterile water for irrigation shall be used to dilute all agents used inside the PEC that require dilution.

(F) At a minimum, the critical area shall be cleaned and disinfected prior to compounding, between batches, and whenever contamination is suspected using sterile alcohol which is allowed to dry immediately prior to compounding.

(18) Environmental Sampling/Testing. The pharmacy shall establish and follow proper controls to ensure environmental quality, prevent environmental contamination, and maintain air quality in all ISO classified areas. Applicable environmental monitoring of air and surfaces must be conducted. Air monitoring must be conducted prior to initial compounding and every six (6) months thereafter. Surface sampling/monitoring must be conducted every six (6) months for Risk Level 2 and every thirty (30) days for Risk Level 3 compounding.

(19) Cytotoxic Drugs.

(A) The following additional requirements are necessary for those licensed pharmacies that prepare cytotoxic drugs to insure the protection of the personnel involved:

1. Cytotoxic drugs shall be compounded in a vertical flow, Class II biological safety cabinet or a CACI. If used for other preparations, the cabinet must be thoroughly cleaned;

2. Protective apparel shall be worn by personnel compounding cytotoxic drugs which shall include disposable masks, gloves, and gowns with tight cuffs;

3. Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile preparations. Chemotherapy preparations should be compounded using a closed system transfer device;

4. Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic waste from the preparation of chemotherapy agents and infectious waste from patients' homes. Disposal of cytotoxic waste shall comply with all applicable local, state, and federal requirements;

5. Written procedures for handling major and minor spills and generated waste of cytotoxic agents must be developed and must be included in the policy and procedure manual; and

6. Prepared doses of cytotoxic drugs must be labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

(20) Remedial Investigations. A remedial investigation shall be required if any environmental monitoring sample demonstrates a colony forming unit (CFU) count that exceeds USP Chapter 797 recommended action levels for the type of sampling. A remedial investigation shall include resampling of all affected areas to ensure a suitable state of microbial control. CSPs and any ingredients used within the compounding process that are part of the remedial investigation shall be quarantined until the results of the investigation are known. The pharmacy shall ensure that no misbranded, contaminated, or adulterated CSP is administered or dispensed for patient use.

(A) If an environmental monitoring sample taken from an ISO-5 classified area exceeds USP 797 action levels, the pharmacy must cease compounding in the affected ISO classified area until resampling shows a suitable state of microbial control has been achieved in the affected area. However, a pharmacy may continue to compound during the remedial investigation if –

1. The affected ISO classified area is cleaned and disinfected by using a germicidal cleaning agent and a sporicidal agent followed by sterile alcohol;

2. The beyond-use date assigned to all preparations is no greater than twelve (12) hours; and

3. The affected ISO classified area is resampled under dynamic conditions. If the resampling exceeds USP Chapter 797 action levels, compounding must cease until resampling shows a suitable state of microbial control has been achieved in the affected area, unless otherwise authorized by the board or board's authorized designee to continue compounding upon a showing the facility can be operated in a manner not to endanger the public safety.

(B) If an environmental monitoring sample taken from an ISO-7 classified buffer area exceeds USP 797 action levels, the pharmacy must cease compounding in the affected ISO classified buffer area until resampling shows a suitable state of microbial control has been achieved in the affected area. However, a pharmacy may continue to compound during the remedial investigation if –

1. The affected ISO classified area is cleaned and disinfected by using a germicidal cleaning agent and a sporicidal agent;

2. The beyond-use date assigned to Risk Level 1 preparations is not greater than twenty-four (24) hours or, for Risk level 2 and 3 preparations, no greater than twelve (12) hours; and

3. The affected ISO classified area is resampled under dynamic conditions. If two (2) consecutive resamplings exceed USP 797 action levels, compounding must cease until resampling shows a suitable state of microbial control has been achieved in the affected area, unless otherwise authorized by the board or board's authorized designee to continue compounding upon a showing the facility can be operated in a manner not to endanger the public health or safety.

(C) The pharmacy shall notify the board in writing within three (3) days of any environmental monitoring sample collected as part of a remedial investigation that exceeds USP 797 action levels.

(21) Recalls. A recall must be initiated when a dispensed CSP is deemed to be misbranded, adulterated, or non-sterile or if end-preparation testing results are out of specification. The pharmacy shall notify the prescriber of the nature of the recall, the problem(s) identified, and any recommended actions to ensure public health and safety. In cases where the CSP has the potential to harm the patient, the same notification shall be provided to all patients that received the recalled CSP(s). Any recall initiated by a pharmacy shall be reported, in writing, to the board within three (3) business days. The pharmacy shall document their activities related to the recall.

AUTHORITY: sections 338.240 and 338.280, RSMo 2016, and sections 338.010 and 338.140, RSMo Supp. 2021. This rule originally filed as 4 CSR 220-2.200. Original rule filed May 4, 1992, effective Feb. 26, 1993. Amended: Filed Oct. 28, 1994, effective May 28, 1995. Rescinded and readopted: Filed Dec. 3, 2002, effective July 30, 2003. Moved to 20 CSR 2220-2.200, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008. Emergency amendment filed July 25, 2016, effective Aug. 4, 2016, expired Feb. 23, 2017. Amended: Filed July 25, 2016, effective Jan. 30, 2017. Emergency amendment filed Aug. 20, 2018, effective Aug. 30, 2018, expired Feb. 28, 2019. Amended: Filed Aug. 20, 2018, effective Feb. 28, 2019. ** Emergency amendment filed April 14, 2021, effective April 28, 2021, expired Feb. 7, 2022. Amended: Filed April 14, 2021, effective Oct. 30, 2021. Emergency amendment filed Feb. 8, 2022, effective Feb. 24, 2022, expired Aug. 22, 2022. Amended: Filed Feb. 8, 2022, effective Aug. 30, 2022.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019, 2021; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

***Pursuant to Executive Order 21-09, 20 CSR 2220-2.200, subsection (10)(B) was suspended from March 20, 2020 through December 31, 2021.*

20 CSR 2220-2.300 Record Confidentiality and Disclosure

PURPOSE: This rule establishes requirements for the confidentiality and disclosure of records related to patient care.

(1) Prescription records, physician orders, and other records related to any patient care or medical condition(s) of a patient that are maintained by a pharmacy in accordance with section 338.100, RSMo shall be considered confidential. Adequate security shall be maintained over such records in order to prevent any indiscriminate or unauthorized use of any written, electronic or verbal communications of confidential information.

(2) Confidential records may only be released to –

(A) The patient;

(B) A health care provider involved in treatment activities of the patient;

(C) Lawful requests from a court or grand jury;

(D) A person authorized by a court order;

(E) Any other person or entity authorized by a patient to receive such information;

(F) For the transfer of medical or prescription information between pharmacists as provided by law;

(G) Government agencies acting within the scope of their statutory authority; or

(H) A person or entity to whom such information may be disclosed under 45 CFR Parts 160, 164, and 165 (the Privacy Standards of the Health Insurance Portability and Accountability Act of 1996) or other applicable state/federal law.

(3) This rule does not change or otherwise alter the authority of the board, its inspectors, or other authorized designees to review, inspect, copy, or take possession of any such records.

(4) Methods to access, transmit, store, analyze, or purge confidential information shall be implemented using procedures generally recognized as secure by experts qualified by training and experience. Procedures shall be in place to ensure that purged confidential information cannot be misused or placed into active operation without appropriate authorization as provided in this rule. Internet connectivity or remote access tied directly to systems containing confidential information must be secure.

AUTHORITY: sections 338.100 and 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-2.300. Original rule filed May 4, 1995, effective Dec. 30, 1995. Rescinded and readopted: Filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed Dec. 15, 2003, effective July 30, 2004. Moved to 20 CSR 2220-2.300, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Nov. 30, 2019.*

**Original authority: 338.100, RSMo 1939, amended 1971, 1990, 1997, 1999, 2010, 2016; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.400 Compounding Standards of Practice

PURPOSE: This rule defines compounding and establishes guidelines for the compounding of drugs.

(1) Compounding is defined as the preparation, incorporation, mixing and packaging, or labeling of a drug or device as the result of a prescriber's prescription or prescription drug order based on the prescriber/patient/pharmacist relationship in the course of professional practice. Compounding may also be defined as the preparation, incorporation, mixing and packaging, or labeling of a drug or device, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing purposes.

(2) Manufacturing is defined as the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance(s) or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices.

(3) Batch compounded preparation is defined as a preparation compounded in advance of receipt of a prescription or a preparation compounded in a supply that will be used on more than one (1) dispensing to a patient or patients or any preparation compounded in excess of the filling of an individual prescription. A batch is a specific quantity of preparation compounded in a single, discrete process, by the same individuals, carried out during one (1) limited time period.

(4) Beyond-use date: A date after which a compounded preparation should not be used and is determined from the date the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their beyond-use dates must be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products.

(5) Compounding Area and Equipment Requirements.

(A) The area(s) used for compounding preparations shall be maintained in a sanitary condition and shall be free of infestation by insects, rodents, and other vermin. Trash shall be held and disposed of in a timely and sanitary manner.

(B) If drug products with special precautions for contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross-contamination.

(C) Equipment used in compounding preparations shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in compounding preparations shall be of suitable composition so that surfaces that contact ingredients, in-process materials, or compounded preparations shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded preparation beyond that desired.

(6) Proper controls shall be maintained over drug products/ingredients, containers, and container closures.

(A) Bulk drugs and other materials used in compounding preparations must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

(B) Pharmacists shall only receive, store, or use drug substances for compounding that have been made and/or distributed by Missouri licensed/registered drug distributors. A bulk drug substance for human use that is not the subject of an applicable United States Pharmacopeia or National Formulary monograph or is not a component of a Federal Drug Administration (FDA) approved drug cannot be used in compounding unless it appears on a list promulgated as a regulation pursuant to section 503A(b)(1)(A)(i)(III) of the Federal Food, Drug, and Cosmetic Act, except as otherwise allowed by the FDA.

(C) Pharmacists shall only use nondrug substances for compounding that are free of any contaminants and which maintain full potency.

(D) Drug products/ingredients, containers, and container closures used in compounding of preparations shall be handled and stored in a manner to prevent contamination.

(E) Drug products/ingredient containers and container closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded preparation beyond the desired result. Container systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded preparation.

(7) Appropriate quality control measures shall be maintained by the pharmacy and its staff over compounding methods.

(A) Such methods shall include the following and shall be followed in the execution of the compounding process. A separate log shall be maintained which includes –

1. Methods for compounding preparations to ensure that

finished preparations have the identity, strength, quality, and purity they purport or are represented to possess;

2. Date of compounding;

3. Identity of the compounding pharmacist;

4. A listing of the drug products/ingredients and their amounts by weight or volume;

5. Description of the compounding process and the order of drug product/ingredient addition, if necessary for proper compounding;

6. The identity of the source, lot number, and the beyond-use date of each drug product/ingredient, as well as an in-house lot number and a beyond-use date for bulk compounded preparations; and

7. An identifying prescription number or a readily retrievable unique identifier for which the compound was dispensed.

(B) Information related to and the methods of compounding shall be available upon request.

(C) Pharmacists may compound preparations in limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely with an established pharmacist/patient/prescriber relationship.

1. Except as otherwise provided by law, compounding preparations in anticipation of receiving prescriptions without an appropriate history of such prescriptions on file or a documented need shall be considered manufacturing instead of compounding of the drug(s) involved. Limited quantities, for purposes of this rule, are further defined as an amount of batched preparation that represents a three- (3-) month supply.

2. Creams, ointments, lotions, liniments, or other compounded preparations intended for external use may be batched in the same manner as provided for in paragraph (7)(C)1. of this rule that represents a one- (1-) year supply.

(D) Any excess compounded preparations shall be stored and accounted for under conditions dictated by its composition and stability characteristics to ensure its strength, quality, and purity. Excess preparations shall be labeled with the name of the drug(s), an in-house lot number, and beyond-use date.

(E) Records as outlined in this rule shall be retained and made readily retrievable for inspection for two (2) years from the date of compounding.

(F) The actual name of each active or therapeutic ingredient contained in a compound shall be listed on the container of any compounded preparation provided to a consumer.

(8) Management of Compounding.

(A) A pharmacist dispensing a compounded preparation is responsible for ensuring the preparation has been prepared, labeled, controlled, stored, dispensed, and distributed properly. The pharmacist is responsible for ensuring that quality is built into the preparation and ensuring –

1. Personnel are capable and qualified to perform their assigned duties;

2. Ingredients used in compounding have their expected identity, quality, and purity. Drug components must meet compendial standards or maintain a certificate of analysis on file when bulk drug substances are involved. Visual inspection of bulk drug substances must be performed;

3. Reasonable assurance that processes are always carried out as intended or specified;

4. Preparation conditions and procedures are adequate for preventing mix-ups or other errors; and

5. All finished preparations, as a condition of release, are individually inspected for evidence of visible particulates or other foreign matter and for container-closure integrity and any other apparent visual defects.

(B) The pharmacy is responsible for developing a drug monitoring system for compounded preparations. The outcome monitoring system shall provide readily retrievable information suitable for the evaluation of the quality of pharmaceutical services including but not limited to reported infection rates, incidence of adverse drug reactions, incidence of recalls, and complaints from prescribers or clients.

(C) A recall must be initiated when a compounded preparation is deemed to be misbranded or adulterated. The pharmacy shall notify the prescriber of the nature of the recall, the problem(s) identified, and any recommended actions to ensure public health and safety.

1. In cases where the compounded preparation has the potential to harm the patient, the same recall notification as provided for in this subsection shall be provided to all patients that have received the recalled compounded preparation(s).

2. Any recall initiated by a pharmacy shall be reported, in writing, to the board within three (3) business days.

(9) The compounding of a preparation that is a copy or essentially a copy of a commercially available product is prohibited except when there is a specific medical need for a particular variation of a commercially available compound for an individual patient as determined by the prescriber, or when a change or modification for a specific patient would produce for that patient a clinically significant difference between the compounded preparation and the comparable commercially available drug product, as determined by the prescribing practitioner. Documentation from the prescriber of the specific medical need or clinically significant difference for a specific patient must be maintained in the pharmacy's records. A prescription that identifies only a patient name and compounded preparation formulation is insufficient documentation for a pharmacy to rely upon to conclude that the prescriber made a determination regarding a specific medical need or clinically significant difference. A different formulation without a documented specific medical need or clinically significant difference is not sufficient.

(A) For purposes of this rule, "essentially a copy of commercially available product" is a compounded preparation that has –

1. The same active pharmaceutical ingredient(s) as the commercially available drug product;

2. The same, similar, or an easily substitutable dosage strength; and

3. The same manner of administration as the commercially available drug product.

(B) For purposes of this rule, "easily substitutable" means the same or similar dosage strength can be achieved by administration of fractional or multiple doses of a commercially available drug product.

(C) When compounding an otherwise commercially available product due to a drug shortage, the pharmacy must confirm and document the commercially available product is not available despite due diligence.

(10) Any alteration, change, or modification to the contents of a commercially manufactured over-the-counter product shall require a prescription or prescription drug order from an authorized prescriber. The compounding of any preparation without a prescription or medication order is prohibited.

(11) Any person shown at any time, either by medical examination or pharmacist determination, to have an apparent illness or open lesion(s) that may adversely affect the safety or quality of a compounded preparation shall be excluded from direct contact with compounded preparations/ingredients, drug product containers, container closures, and in-process materials until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the compounded preparation.

(12) Except as provided by law, pharmacists shall not offer or provide compounded preparations to other pharmacies, practitioners, or entities for subsequent dispensing, distribution, resale, or administration, except in the course of professional practice for a prescriber to administer to an individual patient by a prescription dispensed by the pharmacy. A pharmacist or pharmacy may advertise or otherwise provide information concerning the provision of compounding services; however, no pharmacist or pharmacy shall attempt to solicit business by making specific claims about compounded preparations.

(13) Pharmacies may provide non-patient specific compounded preparations for veterinary use to a Missouri-licensed veterinarian to administer and dispense to the veterinarians's animal patients, provided the following:

(A) The preparation container is labeled with –

1. Pharmacy name, address, and telephone number;
2. Date of distribution;
3. Veterinarian's name;
4. Preparation name, strength, dosage form, and quantity;
5. Name of each active or therapeutic ingredient included in the preparation;
6. Preparation lot/batch number;
7. Preparation beyond-use date; and
8. Statement: "Office Stock Compounded Preparation";

(B) The pharmacy maintains a record of the distribution to the veterinarian;

(C) The pharmacy can retrieve distribution records by specific veterinarian, if requested;

(D) In lieu of paragraph (7)(A)7., the veterinarian's name may be recorded on the compounding log; and

(E) The pharmacy complies with all applicable controlled substance laws and regulations.

(14) In addition to the requirements outlined in this rule, all standards and requirements as outlined in 20 CSR 2220-2.200, Sterile Compounding, must be adhered to whenever compounding involves the need for asceptic procedures or requires the use of or results in an intended sterile pharmaceutical preparation.

AUTHORITY: sections 338.010 and 338.140, RSMo Supp. 2022, and sections 338.240 and 338.280, RSMo 2016. This rule originally filed as 4 CSR 220-2.400. Original rule filed Aug. 25, 1995, effective April 30, 1996. Amended: Filed Dec. 3, 2002, effective July 30, 2003. Moved to 20 CSR 2220-2.400, effective Aug. 28, 2006. Emergency amendment filed March 20, 2019, effective March 30, 2019, expired Jan. 8, 2020. Amended: Filed March 20, 2019, effective Sept. 30, 2019. Amended: Filed March 10, 2023, effective Sept. 30, 2023.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019, 2021; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.410 Class B Hospital Pharmacy Compounding for Drug Shortages

PURPOSE: This rule establishes requirements for Class B hospital pharmacies compounding medication in the event of a drug shortage.

(1) Class B hospital pharmacies may compound and provide medications that are in shortage to patients without a patient-specific prescription, provided –

(A) The pharmacy has confirmed and documented the product is not available despite due diligence;

(B) The medication is compounded for administration to patients in a hospital clinic or facility or in another hospital that is under common control, management, or ownership of the same hospital or hospital system, as defined by section 338.165, RSMo;

(C) The preparation compounded is the same dosage form and strength that is in shortage;

(D) The quantity distributed at one time does not exceed the amount needed to meet the anticipated healthcare practitioner need for seven (7) days based on the hospital's or hospital clinic's/facility's usage;

(E) The pharmacy must stop compounding and distribution once the product is available;

(F) The pharmacy must label the preparation container with –

1. Pharmacy name, address, and telephone number;
2. Date of distribution;
3. Preparation name, strength, dosage form, and quantity;
4. Name of each active or therapeutic ingredient included in the preparation;
5. Preparation lot/batch number;
6. Preparation beyond-use date; and
7. Statement: "Pharmacy Compounded Preparation";

(G) The pharmacy maintains a record of the distribution that is readily available on request of the board or the board's authorized designee and can be retrieved by specific hospital or hospital clinic or facility, if requested;

(H) In lieu of recording an identifying prescription number or a readily retrievable unique identifier, the hospital or hospital clinic or facility name must be recorded on the compounding log;

(I) The pharmacy must comply with all applicable provisions of 20 CSR 2220-2.400. A Class H license and compliance with 20 CSR 2220-2.200 is required for any sterile preparation; and

(J) The pharmacy complies with all applicable controlled substance laws and regulations.

(2) Unless otherwise provided by law or court of competent jurisdiction, the provisions of this rule are only applicable to pharmacy services under the jurisdiction of the board and are not applicable to hospital pharmacy services under the jurisdiction of the Missouri Department of Health and Senior Services pursuant to Chapter 197, RSMo.

AUTHORITY: sections 338.140.1 and 338.210, RSMo Supp. 2022, and section 338.280, RSMo 2016. Original rule filed March 10, 2023, effective Sept. 30, 2023.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.425 Required Pharmacy Reporting

PURPOSE: The purpose of this rule is to establish requirements for reporting compounding information to the Missouri Board of Pharmacy to ensure compliance with state and federal law.

(1) Pharmacies located in Missouri that have distributed or dispensed compounded human drug preparations/products pursuant to prescriptions or medication orders in the previous calendar year, shall annually report the following information on a form provided by the board:

(A) The number of prescriptions or medication orders for compounded human drug preparations/products that the pharmacy distributed or dispensed interstate during the previous calendar year;

(B) The number of prescriptions or medication orders for compounded human drug preparations/products that the pharmacy dispensed (or caused to be dispensed) from the facility in which the drug preparations/products were compounded during the previous calendar year (e.g., not picked up on-site by the patient or the patient's designee);

(C) The number of prescription or medication orders for compounded human drug preparations/products dispensed on-site at the pharmacy during the previous calendar year (e.g., picked up by the patient or the patient's designee);

(D) The sum of the figures from subsections (1)(B) and (1)(C) above; and

(E) The quotient from dividing the figure in subsection (1)(A) by the figure from subsection (1)(D).

(2) If the figure in subsection (1)(E) is greater than five tenths (0.5), the pharmacy shall also report the following information:

(A) The total number of prescription or medication orders for sterile compounded human drugs distributed or dispensed interstate during the previous calendar year;

(B) A list of the states where the pharmacy was licensed during the previous calendar year; and

(C) A list of the states into which the pharmacy distributed compounded human drug preparations/products during the previous calendar year.

(3) The required information shall be reported no later than January 31, each calendar year.

(4) The term "prescription or medication orders for compounded human drug preparations/products" as used above, does not include veterinary drug products, and biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262).

(5) Notwithstanding the above, a pharmacy which participates in and reports all information required by this rule to the National Association of Boards of Pharmacy (NABP) Information Sharing Network shall not be required to also report to the board. Pharmacies reporting to NABP's Sharing Network shall notify the board no later than January 31 each calendar year that information required by this rule has been reported to NABP. A copy of information submitted to NABP pursuant to this rule shall be provided to the board or the board's authorized designee within five (5) business days of a request from the board or authorized board designee.

AUTHORITY: sections 338.010 and 338.140, RSMo Supp. 2020, and sections 338.240 and 338.280, RSMo 2016. Original rule filed Jan. 7, 2021, effective July 30, 2021.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.450 Fingerprint Requirements
(Rescinded August 30, 2013)

AUTHORITY: sections 338.140 and 338.280, RSMo 2000. This rule originally filed as 4 CSR 220-2.450. Original rule filed Jan. 6, 1997, effective July 30, 1997. Amended: Filed April 23, 1998, effective Nov. 30, 1998. Moved to 20 CSR 2220-2.450, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008. Rescinded: Filed Jan. 10, 2013, effective Aug. 30, 2013.

20 CSR 2220-2.500 Nuclear Pharmacy – Minimum Standards for Operation

PURPOSE: This rule defines minimum standards for the operation of nuclear pharmacies and the preparation, labeling, dispensing, delivering, compounding, and repackaging of radiopharmaceuticals pursuant to a prescription drug or medication order. This regulation is intended to supplement other regulations of the Board of Pharmacy, as well as those of other state and/or federal agencies.

(1) Definitions.

(A) "Agreement state" means any state that has entered into an agreement under subsection 274b of the Atomic Energy Act of 1954, as amended, in which the United States Nuclear Regulatory Commission has relinquished to such states the majority of its regulatory authority over source material, by-product, and special nuclear material in quantities not sufficient to form a critical mass.

(B) "Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

(C) "Authorized address or location" means the building or buildings that are identified on the license and where by-product material may be received, prepared, used, or stored as defined by 10 CFR 35.2 or a temporary job site for providing mobile nuclear medicine services in accordance with 10 CFR 35.80.

(D) "Authorized nuclear pharmacist" (ANP) means a pharmacist who holds a current license issued by the board and who is either certified as a nuclear pharmacist by the Board of Pharmacy Specialties, has attained status as an authorized nuclear pharmacist, or an authorized user of radioactive material, as specified by the Nuclear Regulatory Commission or Agreement State regulations, including, but not limited to, 10 CFR 35.55, 35.57, and 35.59.

(E) "Contingency prescription drug order" means a radioactive prescription drug order issued for contingency material for a diagnostic purpose.

(F) "Controlled access area" means an area outside of the restricted area but inside the pharmacy, access to which will be limited to the public.

(G) "NRC" means the United States Nuclear Regulatory Commission.

(H) "Nuclear pharmacy" means the location that provides radiopharmaceutical services and where radiopharmaceuticals and chemicals within the classification of legend drugs,

are prepared, compounded, repackaged, dispensed, stored, sold, or used for nuclear medicine procedures. The term "nuclear pharmacy" does not include the nuclear medicine facilities of hospitals or clinics where radiopharmaceuticals are compounded or dispensed to patients under the supervision of a licensed physician, authorized by the Nuclear Regulatory Commission or Agreement State regulations. Nothing in this rule shall be construed as requiring a licensed clinical laboratory, which is also licensed by the Nuclear Regulatory Commission or Agreement State to handle radioactive materials, to obtain the services of a nuclear pharmacist, or to have a pharmacy permit, unless the laboratory is engaged in the commercial sale or resale of radiopharmaceuticals.

(I) "Nuclear pharmacy technician" means a person who has successfully completed a nuclear pharmacy technician training program provided by an accredited college program or meets the American Pharmacist's Association's (APhA) Guidelines for Nuclear Pharmacy Technician Training Program or an equivalent company sponsored program that meets APhA guidelines for nuclear pharmacy technician training.

(J) "Practice of nuclear pharmacy" means a patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals and other drugs.

(K) "Preparing of radiopharmaceuticals" means the addition of a radioactive substance, or the use of a radioactive substance in preparation of a single-dose or multiple-dose medication, pursuant to the prescription drug order/ contingency prescription drug order. Such preparing of radiopharmaceuticals includes, but is not limited to, loading and eluting of radionuclide generators, using manufactured reagent kits to prepare radiopharmaceuticals, preparing reagent kits, aliquoting reagents, and conducting quality control tests of radiopharmaceuticals.

(L) "Prescription drug order" means a prescription drug order issued for a specific patient for a diagnostic or therapeutic purpose.

(M) "Quality control testing" means, but is not limited to, the performance of appropriate chemical, biological, physical, radiochemical, and radionuclidic purity tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals.

(N) "Quality assurance procedures" means all activities necessary to assure the quality of the process used to provide radiopharmaceutical services, including authentication of product history and maintenance of all records as required by pertinent regulatory agencies.

(O) "Radiopharmaceutical" means any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or nuclide generator which is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides. The term "radiopharmaceutical" also includes any biological product which is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

(P) "Radiopharmaceutical services" means, but not limited to, the procurement, storage, handling, compounding, preparation, repackaging, labeling, quality control testing, dispensing, delivery, transfer, record-keeping, and disposal of radiochemicals, radiopharmaceuticals, and ancillary drugs; the participation in radiopharmaceutical selection and radiopharmaceutical utilization review, and also includes quality assurance procedures, radiological healthcare activities, any consulting activities associated with the use of radiopharmaceuticals, and any other activities required for provision of radiopharmaceutical care; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation management, and control of a nuclear pharmacy.

(Q) "Restricted area" means an area within the pharmacy that is secured from the Controlled Access Area and to which access is limited for the purpose of protecting individuals against exposure to radiation and radioactive materials.

(R) "Therapeutic prescription drug order" means a radioactive prescription drug issued for a specific patient for a therapeutic purpose.

(S) "Unit dose container" (e.g., shield or "pig") means a container designed to hold doses of radiopharmaceutical agents and to prevent or minimize/reduce the emission of radiation or radioactive materials by using appropriate shielding materials.

(2) General Requirements for Pharmacies Providing Radiopharmaceutical Services.

(A) No person may receive, acquire, possess, prepare, compound, dispense, repackage, transfer, dispose of, or manufacture for sale or resale any radiopharmaceutical except in accordance with the provisions of this rule and the conditions of rules and regulations promulgated by the Nuclear Regulatory Commission or applicable Agreement State.

(B) Nuclear pharmacies shall post, in a conspicuous area of the pharmacy, a copy of the current registration with the Board of Pharmacy and a copy of the most current U.S. NRC or applicable Agreement State license which details a listing of its authorized nuclear pharmacists. A reference to its specific location within the pharmacy is acceptable.

(C) A nuclear pharmacy must have on file a copy of the current radioactive materials license for the licensed facility requesting any radiopharmaceutical before the radioactive drug is permitted to be dispensed to that facility. The radiopharmaceutical may only be delivered to the authorized addresses or locations listed in, or temporary job sites as authorized by, the NRC/Agreement State license. The authorized physician ordering radiopharmaceuticals is hereby recognized as the patient's authorized designee for delivery purposes. This section is an exemption for Class E pharmacies to 20 CSR 2220-2.013(2) Prescription Delivery Requirements, which details authorized delivery sites.

(D) Nuclear pharmacies shall comply with any applicable requirements of other governing agencies regarding its daily operations and the disposal of any biohazardous medical waste. Appropriately labeled and, when required shielded, disposal containers shall be used for radioactive and biohazardous waste from the preparation or the return of radiopharmaceuticals. Disposal of biohazardous waste shall comply with all applicable local, state, and federal requirements.

(E) Any reusable unit dose container that is returned shall be considered to be contaminated. No pharmacy shall utilize a reusable unit dose container for radioactive doses without either an effective process to decontaminate the container of biohazardous substances or an effective mechanism to avoid contamination of the container. No pharmacy may reuse a unit dose container that remains contaminated with blood or other

biohazardous substances.

(F) A Class E pharmacy may accept returns and waste as authorized by the NRC/Agreement State regulations.

(3) Permits. Any pharmacy providing radiopharmaceutical services must obtain a Class E radiopharmaceutical permit from the board. Nuclear pharmacies preparing, compounding or repackaging sterile preparations must have Class H Sterile Product Compounding on their permit.

(A) A permit to operate a nuclear pharmacy shall only be issued to a person who is, or who employs, an authorized nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of an authorized nuclear pharmacist. The pharmacist-in-charge shall be an authorized nuclear pharmacist and be responsible for all operations of the pharmacy.

(B) The permit to operate a nuclear pharmacy is effective only if the pharmacy also holds a current Nuclear Regulatory Commission and/or Agreement State radioactive materials license. Copies of the most recent regulatory inspection reports must be made available upon request to the board for inspection.

(C) The nuclear pharmacist-in-charge shall notify the Board of Pharmacy by letter of the outcome of any hearings under state or federal laws or regulations governing radioactive materials involving or against the pharmacy location licensed by the board. Notification must be within thirty (30) days of the date of the outcome.

(4) Space, Security, Record-Keeping, and Equipment.

(A) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services provided, and as required by the Nuclear Regulatory Commission or Agreement State radioactive materials license or as required by 20 CSR 2220-2.200 Sterile Compounding, 20 CSR 2220-2.400 Compounding Standards of Practice or other applicable rules of the board. Radionuclide generators shall be stored and operated in an ISO 8 or better classified area. All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas:

1. Radiopharmaceutical nonsterile and sterile preparation/dispensing area;
2. Radioactive material shipping/receiving area;
3. Radioactive material storage area; and
4. Radioactive waste decay area.

(B) The nuclear pharmacy restricted area shall be secured against unauthorized personnel and must be totally enclosed and lockable.

(C) Nuclear pharmacies shall maintain records of acquisition, inventory, preparing, compounding, repackaging, dispensing, distribution, and disposition of all radioactive drugs and other radioactive materials in accordance with State Board of Pharmacy and Nuclear Regulatory Commission or Agreement State rules/requirements.

(D) Nuclear pharmacies shall prepare, compound, repackage, and dispense radiopharmaceuticals in accordance with accepted standards of nuclear pharmacy practice and in compliance with 20 CSR 2220-2.200 Sterile Compounding and 20 CSR 2220-2.400 Compounding Standards of Practice. Appropriate safety and containment techniques for preparing, repackaging, and compounding radiopharmaceuticals shall be used in conjunction with the aseptic techniques required for sterile preparations. Only authorized nuclear pharmacists, intern pharmacists, and nuclear pharmacy technicians may prepare, compound, repackage, or dispense radiopharmaceuticals.

(E) Unless required by other rule or applicable law, all records required by this rule must be maintained for two (2) years and must be made available to the board or its representative upon request.

(5) Dispensing, Packaging, Labeling.

(A) A radiopharmaceutical shall be dispensed only to a practitioner or facility authorized by the Nuclear Regulatory Commission or an Agreement State to possess, use and administer such drug, provided that a radiopharmaceutical may be transferred to a person who is authorized to possess the drug in accordance with the regulations of the NRC/Agreement State. A radiopharmaceutical shall not be dispensed directly to a patient. A nuclear pharmacy may distribute radionuclide elutions to other authorized users to meet a drug shortage.

(B) The amount of radioactivity shall be determined by dose calibrator, appropriate radiometric methods, or decay calculation methods for each individual dose immediately prior to dispensing.

(C) Radiopharmaceuticals are to be dispensed only upon a non-refillable prescription drug order or a contingency prescription drug order from a practitioner or facility authorized by the Nuclear Regulatory Commission or Agreement State to possess, use, and administer radiopharmaceuticals or the practitioner's/facility's designated agent. The prescription drug order/contingency prescription drug order must be taken by an authorized nuclear pharmacist, intern pharmacist, or nuclear pharmacy technician under the supervision of an authorized nuclear pharmacist. Only authorized nuclear pharmacists may receive verbal therapeutic prescription drug orders. The prescription record shall contain all information as required in 20 CSR 2220-2.018 Prescription Requirements and shall also include:

1. The date of dispensing and the calibration time of the radiopharmaceutical; and
2. The patient's name for therapeutic prescription drug orders and blood-containing products.

(D) The unit dose container of a radiopharmaceutical to be dispensed shall be labeled with –

1. The name and address of the pharmacy;
2. The name and address of the authorized prescriber/facility where the prescription drug order/contingency prescription drug order is to be administered;
3. The date of dispensing and a unique readily retrievable identifier;
4. The standard radiation symbol;
5. The words "Caution Radioactive Material";
6. The name of the procedure, if known;
7. The name or generally recognized and accepted abbreviation of the radiopharmaceutical, radionuclide, and chemical form;
8. The requested amount of radioactivity at the calibration date and time;
9. The radiopharmaceutical beyond-use date;
10. The quantity dispensed;
11. If applicable, Molybdenum-99 content to *United States Pharmacopoeia* (USP) limits of <0.15uCi Mo-99 per 1mCi Tc-99m at time of administration or product expiration; and
12. The patient name or the words "Physician's Use Only," "Contingency Prescription Drug Order," "Per Physician's Order," or similar wording in the absence of a patient name. If no patient name is used, the pharmacy must be able to retrieve the name of the patient from the authorized prescriber/facility

within three (3) days if requested. When the prescription is for a therapeutic or blood-containing radiopharmaceutical, the patient name shall appear on the label.

(E) The immediate inner container label of a radiopharmaceutical to be dispensed shall be labeled with –

1. The standard radiation symbol;
2. The words "Caution Radioactive Material";
3. The identity of the radiopharmaceutical;
4. The unique, readily retrievable identifier of the radiopharmaceutical; and
5. The patient's name, if known or the words "Physician's Use Only," "Contingency Prescription Drug Order," "Per Physician's Order," or similar wording in the absence of a patient name.

(F) Radiopharmaceuticals approved by the United States Food and Drug Administration are not subject to the unit dose container labeling requirements in subsection (D) or the radiometric measurement requirements of this rule if the nuclear pharmacy does not process the radioactive drugs in any manner nor violate the original manufacturer product packaging/labeling.

(6) Reference Manuals. Each nuclear pharmacy shall have a current copy of, or electronic access to –

(A) Applicable reference materials commensurate with the scope of services provided;

(B) A current print or electronic edition of statutes and rules governing the pharmacy's practice, including, but not limited to, Chapters 338 and 195, RSMo, 20 CSR 2220 and, if applicable, 19 CSR 30 governing controlled substances; and

(C) Agreement State and/or NRC regulations governing the safe storage, handling, use, dispensing, transport, and disposal of radioactive material, including, but not limited to, Title 10 and Title 49 of the United States Code of Federal Regulations.

(7) Special Conditions.

(A) To comply with NRC exposure guidelines of keeping radiation exposure as low as reasonably achievable (ALARA), the required pharmacist verification of the preparation shall be deemed satisfied if a pharmacist has previously verified the correct ingredients and calculations. Additionally, a pharmacist must verify the accuracy of the prescription/drug order information used and the label information prior to dispensing.

(B) At its discretion, for a pharmacy preparing, compounding, repackaging, or dispensing radiopharmaceuticals the board may grant an exemption to regulation requirements that do not pertain to the practice of nuclear pharmacy for a time period designated by the board if such exemption is not contrary to other law and the exemption will provide equal or greater protection of the public safety, health, or welfare. Exemption requests must be submitted in writing and identify the specific exemption requested, the grounds for exemption, the requested exemption length, and any proposed procedures or safeguards for protecting the public safety, health, or welfare if the exemption is approved. If deemed appropriate, the board may grant an exemption to all nuclear pharmacies based on one (1) pharmacy's request.

AUTHORITY: sections 338.210, 338.220, 338.240, 338.250, 338.280, and 338.350, RSMo 2016, and section 338.330(3), RSMo Supp. 2018. This rule originally filed as 4 CSR 220-2.500. Original rule filed Sept. 2, 1997, effective April 30, 1998. Moved to 20 CSR 2220-2.500, effective Aug. 28, 2006. Amended: Filed April 23, 2019, effective Nov. 30, 2019.*

**Original authority: 338.210, RSMo 1951, amended 2001, 2011; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014; 338.240, RSMo 1951, amended 2011; 338.250, RSMo 1951, amended 1990, 1998; 338.280, RSMo 1951, amended 1971, 1981; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-2.600 Standards of Operation for a Class F: Renal Dialysis Pharmacy

PURPOSE: This rule defines minimum standards for a Class F: Renal Dialysis Pharmacy.

(1) A Class F pharmacy (renal dialysis) shall be limited in scope to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address. Pharmacy services and dialysis supplies and products provided by a Class F pharmacy shall be limited to the distribution and delivery of drugs and devices as provided within this rule. All drugs and devices must be ordered by an authorized prescriber for administration or delivery to a person with chronic kidney failure for self-administration at the person's home or specified address. All dialysis supplies and products provided by a Class F pharmacy shall be prepackaged and covered by an approved New Drug Application (NDA) or 510(k) application issued by the Food and Drug Administration (FDA).

(2) A Class F pharmacy shall maintain a pharmacist-in-charge on a consultant basis who shall review pharmacy operations at least weekly. Class F pharmacies shall ensure:

(A) Use of legend drugs and devices that are provided to a person for the treatment of chronic kidney disease for self-administration at the person's home or specified address are under the professional supervision of an appropriate practitioner licensed under Missouri law;

(B) Only drugs and devices that have been ordered by an authorized prescriber and are included on the list of approved formulary drugs and devices are provided to patients;

(C) No drugs or devices are dispensed to a patient until adequate training in the proper use and administration of such products has been completed;

(D) Proper documentation of drug and device distributions and deliveries are maintained by the Class F pharmacy and are made available upon request to practitioners involved in the care of the patient and to board of pharmacy representatives;

(E) A policy and procedure manual is maintained that is available for inspection by board of pharmacy personnel. The manual shall include a quality assurance program with which to monitor the qualifications, training and performance of personnel; and

(F) The pharmacist-in-charge is responsible for the drug/device delivery system and for establishing a written protocol for the implementation of the delivery system including methods for supervising drug/device deliveries to patients of the pharmacy.

1. Any written protocols shall be available for inspection by board of pharmacy personnel.
2. Any changes to the policy and procedure manual or to written protocols must be approved by the pharmacist-in-charge.

(3) A Class F pharmacy may deliver products to a person with chronic kidney failure only upon the receipt of a valid prescription from an authorized prescriber specifying or including:

(A) Documents that the intended recipient will require such products for the appropriate treatment of the disease and that the intended recipient has been trained in home dialysis therapy;

(B) The duration of the prescriber's order, not to exceed one (1) year, including all authorized refills; and

(C) The name and product code of each product prescribed and the quantity prescribed.

(4) Personnel of the pharmacy shall assemble the products to be delivered pursuant to the prescriber's order(s). In assembling such products for delivery, the pharmacy shall take steps necessary to assure the following:

(A) The code numbers and quantities of the products assembled match the code numbers identified in the prescriber's order(s);

(B) Any products bearing an expiration date have a minimum of three (3) full months of shelf-life remaining;

(C) A visual inspection is completed of all drugs and devices for compliance with the prescriber's order(s) and with all labeling requirements as set forth in 338.059, RSMo. Manufacturer sealed case lots shall be labeled with the name of the patient, date, and a control number that serves as a unique patient identifier number; and

(D) Products ordered by a prescriber and provided to patients of the pharmacy shall be delivered either by personnel of the pharmacy or by a carrier authorized by the pharmacy.

1. Upon the delivery to patients of any drugs/devices, pharmacy personnel or the approved carrier shall confirm receipt by the patient or the patient's designee and that the number of units delivered equals the number of units identified by documentation supplied by the pharmacy.

(5) Class F pharmacies shall ensure:

(A) The license of the pharmacy is displayed in plain view at the pharmacy location;

(B) The pharmacy is open such hours as are necessary to safely and effectively dispense and deliver supplies to those persons designated by the applicable prescriber;

(C) The pharmacy maintains sufficient space and storage capabilities as necessary to carry out its operations; and

(D) All drugs and/or devices shall be properly identified and any outdated, misbranded or adulterated items shall be segregated from the active inventory within a clearly separate and defined area and held separately until the item is destroyed or returned to a licensed drug distributor.

AUTHORITY: sections 338.220 and 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-2.600. Original rule filed Jan. 20, 1998, effective Aug. 30, 1998. Moved to 20 CSR 220-2.600, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Nov. 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.650 Standards of Operation for a Class J: Shared Services Pharmacy

PURPOSE: The purpose of this rule is to establish standards for Class J: Shared Services pharmacies.

(1) Class J Shared Services. A Class J Shared Services permit is required if two (2) or more pharmacies are engaged in, or have an arrangement to provide, functions related to the practice of pharmacy for or on behalf of the other pharmacy. These functions may include, but are not limited to, prescription/order receipt, prescription/order clarification or modification, obtaining prescriber authorization, data entry, compounding, dispensing, pharmacist verification, patient counseling, patient profile maintenance, medication therapy services, medication administration, drug utilization review (DUR), and obtaining refill authorization. All pharmacies participating in the shared services arrangement must have a Class J permit.

(A) Pharmacies may perform Class J Shared Services provided the parties –

1. Have the same owner or have a written contract outlining the services to be provided and the responsibilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations;

2. Maintain a separate Class J classification for each location involved in providing shared services; and

3. Either share a common database or have access to each pharmacy's prescription records and patient profiles and records, as needed to safely and properly perform the shared services activities.

(B) Class-J pharmacies operating in compliance with this section are exempt from the requirements of 20 CSR 2220-2.120 and 20 CSR 2220-6.030(4) when transferring prescription information between themselves. A Class-J permit is not required to transfer an individual prescription as authorized by 20 CSR 2220-2.120 pursuant to a request by the patient or the patient's authorized designee.

(C) The parties performing Class J Shared Services shall maintain a detailed written description of authorized shared services that includes the name, address, and permit number(s) of all pharmacies involved. The parties must maintain a current and accurate policy and procedure manual that includes, but is not limited to, the following:

1. Policies and procedures that identify the duties and responsibilities of each pharmacy including any functions identified in section (1). The required policies and procedures must also identify the pharmacy responsible for –

A. Verifying prescription/medication order accuracy and validity;

B. Data entry verification;

C. Drug utilization review as required by 20 CSR 2220-2.195;

D. Final product verification; and

E. Patient counseling;

2. A mechanism for tracking the prescription or medication order during each step in the process;

3. Security provisions for protecting the confidentiality and integrity of patient information;

4. Policies and procedures to ensure the safe and appropriate delivery of prescription drugs in compliance with 20 CSR 2220-2.013; and

5. A designation of the pharmacy responsible for offering patient counseling as required by 20 CSR 2220-2.190 and federal law. For purposes of section 338.059, RSMo, the name and address of either the pharmacy responsible for offering patient counseling or the pharmacy responsible for dispensing to the patient may be listed on the label as designated by the pharmacies by contract.

(D) Each pharmacy involved in a Class-J arrangement must maintain a quality assurance program that is designed to objectively and systematically monitor and evaluate the quality and appropriateness of pharmacy services and resolve identified problems.

(E) Compounding may only be performed pursuant to a Class-J pharmacy arrangement pursuant to a patient-specific prescription or in anticipation of a patient-specific prescription as authorized by 20 CSR 2220-2.200 and the rules of the board.

(F) A Class-J permit is not required for pharmacists performing non-dispensing activities authorized by 20 CSR 2220-6.050 outside of a licensed pharmacy.

(2) A Class J Shared Services permit shall not be required if a completed and labeled prescription is delivered from a Missouri licensed pharmacy to another Missouri licensed pharmacy for administration by a pharmacist or other licensed health care professional to the patient on the same premises or physical location as the pharmacy.

(A) The exemption recognized in this subsection only applies if a completed and labeled prescription is delivered to the receiving pharmacy.

(B) If additional manipulation or compounding is required by the receiving pharmacy, receipt of a prescription or order is required and the receiving pharmacy must dispense the product as their own prescription/order. All prescription requirements, record keeping, compounding, and labeling requirements must be met.

(C) The receiving pharmacy must maintain documentation of the medication received, the name and address of the pharmacy providing the medication, the date of receipt, and the patient's name.

(D) The receiving pharmacy is responsible for ensuring compliance with all applicable patient counseling requirements.

(E) For purposes of this rule, administration is defined as applying or introducing medication to the body of a patient, whether by injection, infusion, inhalation, ingestion, or other means.

(F) Medication administered by a pharmacist must be performed in compliance with all applicable provisions of law.

(G) Notwithstanding any other provision of this rule, licensees shall comply with all applicable controlled substance laws and regulations, including, but not limited to, all applicable security and record keeping requirements.

(3) A Class J Shared Services permit is not required for pharmacies that have an arrangement to provide only initial dispensing services for a Class C pharmacy, as allowed under 20 CSR 2220-2.120(4).

(4) A pharmacy participating in Class J Shared Services with a pharmacy that is not under common ownership must notify patients that his/her prescription or medication order may be filled or compounded by another pharmacy.

(5) All records required by this rule including all policy and procedure manuals, contracts, quality assurance documentation, or other agreements must be maintained for two (2) years and must be made available to the board or its representative upon request.

AUTHORITY: sections 338.240 and 338.280, RSMo 2016, and sections 338.140, 338.210, and 338.220, RSMo Supp. 2021. This rule originally filed as 4 CSR 220-2.650. Original rule filed Nov. 30, 2001, effective June 30, 2002. Amended: Filed Dec. 3, 2002, effective June 30, 2003. Moved to 20 CSR 2220-2.650, effective Aug. 28, 2006. Emergency amendment filed July 27, 2017, effective Aug. 6, 2017, expired Feb. 22, 2018. Amended: Filed July 27, 2017, effective Jan. 30, 2018. ** Amended: Filed Aug. 23, 2021, effective Feb. 28, 2022.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014, 2020; 338.240, RSMo 1951, amended 2011; and 338.280, RSMo 1951, amended 1971, 1981.*

***Pursuant to Executive Order 21-09, 20 CSR 2220-2.650 was suspended from March 20, 2020 through December 31, 2021.*

20 CSR 2220-2.675 Standards of Operation/Licensure for Class L Veterinary Pharmacies

PURPOSE: This rule defines standards for a Class L veterinary pharmacy.

(1) A Class A or a Class L pharmacy permit shall be required for any entity engaged in the sale, dispensing, or filling of a legend drug for use in animals that must only be dispensed by prescription under state or federal law. For purposes of this rule, a legend drug shall be defined as provided by 21 USC section 353.

(2) Class A Pharmacies. Class A permit holders shall comply with all laws/rules applicable to Class A pharmacies, provided a Class A pharmacy shall comply with sections (7) and (8) of this rule when legend drugs are dispensed for animal use.

(3) Class L Pharmacies. A Class L pharmacy shall dispense, sell, or provide legend drugs only for animal use. Except as otherwise provided in this rule, a Class L pharmacy shall comply with all applicable state and federal pharmacy and controlled substance laws/rules including, but not limited to, all applicable provisions of Chapter 338, RSMo, and the rules of the board.

(4) Pharmacy Operations. A Class L pharmacy shall comply with 20 CSR 2220-2.010, with the following allowed modifications:

(A) The pharmacy permit shall be displayed in plain view at the pharmacy location;

(B) The pharmacy shall maintain sufficient space, equipment, and storage capabilities as necessary to carry out its operations;

(C) Legend drugs shall be properly identified and stored in a defined area within the pharmacy;

(D) Legend drugs shall be stored in a clean and sanitary designated area and within temperature requirements as provided for by the manufacturer or the latest edition of the United States Pharmacopoeia (USP);

(E) The pharmacy shall maintain a current reference manual related to veterinary drugs that complies with 20 CSR 2220-2.010(1)(D);

(F) Appropriate sewage disposal must be available within the pharmacy and a hot and cold water supply shall be accessible to pharmacy staff. If compounding is performed, the hot and cold water supply shall be located within the pharmacy;

(G) Pharmacy compounding shall comply with 20 CSR 2220-2.200, 20 CSR 2220-2.400, and all other applicable provisions of state/federal law;

(H) All dispensing errors shall be documented in the pharmacy's records;

(I) Animals shall not be allowed in the designated area where legend drugs are stored or maintained; and

(J) The pharmacist-in-charge shall be notified within twenty-four (24) hours after a dispensing error is learned by pharmacy staff. Documentation of notification shall be maintained in the

pharmacy's prescription records.

(5) A Class L pharmacy shall designate a pharmacist-in-charge as required by 20 CSR 2220-2.010(1)(M). The pharmacist-in-charge shall be responsible for supervising pharmacy operations and ensuring compliance with the provisions of this rule and all applicable state/federal laws. Except as otherwise provided in this rule, the pharmacist-in-charge shall also –

(A) Ensure legend drugs are only sold, dispensed, or filled by the pharmacy for animal use;

(B) Ensure legend drugs have been ordered/prescribed by an authorized prescriber; and

(C) Maintain a policy and procedure manual for pharmacy operations. The policy and procedure manual shall be reviewed annually by the pharmacist-in-charge. The manual shall be available for inspection by board personnel and shall include policies and procedures for:

1. Accepting, compounding, dispensing, or filling prescriptions;

2. Accepting, dispensing, or filling prescriptions in the pharmacist's absence;

3. Drug storage and security;

4. Handling drug recalls;

5. Procedures for offering patient/client counseling;

6. If applicable, procedures for dispensing or providing prescriptions in a pharmacist's absence pursuant to section (8) of this rule;

7. Contacting the pharmacist-in-charge for consultation during the pharmacy's business operations or in the event of an emergency; and

8. Reporting and handling dispensing errors. The pharmacist-in-charge shall be notified of a dispensing error within twenty-four (24) hours after the error is learned by pharmacy staff. Policies/procedures shall include the manner of notification.

(6) A pharmacist shall not be required to be physically present on-site during the business operations of a Class L pharmacy if the pharmacist-in-charge reviews the activities and records of the pharmacy operations on a monthly basis to ensure compliance with this rule. This exemption shall not apply if the pharmacy sells, dispenses, or otherwise provides controlled substances. The date of the pharmacist-in-charge review shall be documented and maintained at the pharmacy.

(7) To be valid for purposes of dispensing, legend drug prescriptions for animal use shall conform to all requirements of sections 338.056 and 338.196, RSMo, and shall contain the following:

(A) The date issued;

(B) The client's/owner's name and the class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated;

(C) The prescriber's name, if an oral prescription, or signature, if a written prescription;

(D) Name, strength, and dosage form of drug and directions for use;

(E) The number of refills, when applicable;

(F) The quantity prescribed in weight, volume, or number of units;

(G) The address of the prescriber and the patient when the prescription is for a controlled substance;

(H) Whether generic substitution has been authorized;

(I) The prescriber's Drug Enforcement Administration (DEA) number when the prescription is for a controlled substance; and

(J) Controlled substance prescriptions shall comply with all requirements of federal and state controlled substance laws.

(8) Dispensing. A Class L pharmacy may accept, fill, enter, dispense, or otherwise provide non-controlled legend drugs for animal use in the absence of a pharmacist, provided the pharmacist-in-charge shall review the prescription record for each such prescription on a monthly basis. The review shall be documented as provided in section (6) of this rule. For purposes of 20 CSR 2220-2.010(3), the dispensing pharmacist shall be identified as the pharmacist-in-charge unless dispensed by another licensed pharmacist.

(A) Legend drugs may only be compounded for use in animals when a pharmacist is present on site.

(B) Clients must be offered an opportunity to consult with a pharmacist as required by 20 CSR 2220-2.190. If the pharmacist is not present on site, a written offer to counsel with a contact telephone number for a pharmacist shall be supplied with the medication.

(9) Labeling. Prescriptions must be labeled as required by section 338.059, RSMo. Prescription labels may be manually written and numbered and shall include:

(A) The class, species, or identification of the animal, herd, flock, pen, lot, or other group being treated; and

(B) If applicable, the veterinarian's specified withdrawal, withholding, or discard time for meat, milk, eggs, or any other food which might be derived from the treated animal(s).

(10) Records. Class L pharmacy records shall be maintained as required by Chapter 338, RSMo, and the rules of the board, including, 20 CSR 2220-2.018 and 20 CSR 2220-2.080.

(A) The information specified in section (7) of this rule shall be required and recorded on all handwritten, telephone, oral, and electronically produced prescriptions that are processed for dispensing by a pharmacist/pharmacy. If applicable, prescription records shall also include the veterinarian's specified withdrawal, withholding, or discard time identified in section (9) of this rule.

(B) Any change or alteration made to the prescription dispensed based on contact with the prescriber shall be documented in the pharmacy's prescription records. This shall include, but is not limited to, a change in quantity, directions, number of refills, or authority to substitute a drug.

(C) The pharmacy's prescription records shall identify any prescription dispensed in a pharmacist's absence pursuant to section (8) of this rule.

(11) A Class L pharmacy shall comply with all applicable state or federal controlled substance laws.

(12) The provisions of this rule shall not be applicable to the sale of medication for use in animals that may lawfully be dispensed without a prescription nor shall this rule be construed to require licensure for entities solely engaged in selling, dispensing, or providing medications authorized for dispensing without a prescription.

(13) The provisions of this rule shall not prohibit or interfere with any legally registered practitioner of veterinary medicine in the compounding, administering, prescribing, or dispensing of their own prescriptions, medicine, drug, or pharmaceutical product to be used for animals.

AUTHORITY: sections 338.056, 338.059, 338.196, 338.250, 338.280, and 338.343, RSMo 2000, and sections 338.010, 338.055, 338.140, 338.150, 338.210, 338.220, and 338.240, RSMo Supp. 2011. Emergency rule filed Aug. 29, 2011, effective Sept. 8, 2011, expired March 5, 2012. Original rule filed Aug. 29, 2011, effective March 30, 2012.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011; 338.055, RSMo 1971, amended 1978, 1981, 1986, 1998, 2001, 2004, 2011; 338.056, RSMo 1978, amended 1996; 338.059, RSMo 1971, amended 1973, 1978, 1997; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011; 338.196, RSMo 1991; 338.210, RSMo 1951, amended 2001, 2011; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2011; 338.240, RSMo 1951, amended 2011; 338.250, RSMo 1951, amended 1990, 1998; 338.280, RSMo 1951, amended 1971, 1981; and 338.343, RSMo 1989, amended 1993.*

20 CSR 2220-2.680 Class R-Remote Dispensing Site Pharmacy

PURPOSE: This rule defines licensing requirements and compliance standards for Class-R Remote Dispensing Site pharmacies.

(1) Definitions.

(A) "Community Mental Health Center" – A community mental health center as defined by 42 CFR section 410.2, section 205.975, RSMo, or the Missouri Department of Mental Health.

(B) "Federally qualified health center" – A federally qualified health center as defined by 42 U.S.C. section 1396d(l)(2)(B), as amended.

(C) "Intern Pharmacist" – An individual who holds a current and active Missouri intern pharmacist license and has completed employer approved training in the activities to be performed at the Class R pharmacy and has an initial and annual documented assessment of competency.

(D) "Outpatient Clinic" – A facility where healthcare services are provided by a licensed healthcare provider on the facility's premises to patients who are not hospitalized or admitted to the outpatient clinic for greater than twenty-three (23) hours.

(E) "Qualified Pharmacy Technician" – A currently registered Missouri pharmacy technician who –

1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies;

2. Has completed employer approved training in the activities to be performed at the Class R pharmacy and has an initial and annual documented assessment of competency; and

3. Has assisted in the practice of pharmacy as a registered pharmacy technician in the state of Missouri for a minimum of one (1) year.

(F) "Remote Dispensing Site Pharmacy" – Any location in this state where the practice of pharmacy occurs that is staffed by one (1) or more qualified pharmacy technicians or intern pharmacists whose activities are supervised by a pharmacist at a supervising pharmacy that is under common ownership through a continuous real-time audio and video link. A remote dispensing site pharmacy does not include a dispensing prescriber's office or an automated device.

(G) "Retail Pharmacy" – A pharmacy licensed by the board that is open to, and offers pharmacy services to, the general public.

(H) "Rural Health Clinic" – A rural health clinic as defined by the federal Rural Health Clinic Services Act, PL. 95-210, as amended.

(I) "Supervising pharmacy" – A Missouri licensed pharmacy located in this state or approved by the board that oversees the dispensing activities of a Class R pharmacy.

(2) A Class R pharmacy permit is required for any Missouri location operating, or offering to operate, as a remote dispensing site pharmacy in Missouri. Applications for a Class R permit must be submitted on a form approved by the board with the pharmacy permit fee, in accordance with 20 CSR 2220-2.020.

(A) Class R pharmacy permits expire and must be renewed, as provided by Chapter 338, RSMo and 20 CSR 2220-2 for pharmacy permits. Renewal applications must be submitted on a form approved by the board with the applicable renewal fee.

(B) Class R pharmacies must be located at least ten (10) miles away from an existing retail pharmacy unless the Class R pharmacy is part of a community mental health center, federally qualified health center, rural health clinic, or outpatient clinic setting. Requests to waive the mileage requirement may be submitted to the board in writing along with documentation demonstrating how the proposed remote dispensing site pharmacy will promote public health. The board will consider the following factors when determining whether to grant a waiver request:

1. The availability of pharmacy services in the proposed pharmacy area;

2. The nature of proposed Class R pharmacy services;

3. Benefits or risks to patient care;

4. The applicant's and supervising pharmacy's experience and compliance history; and

5. Any other factor that may benefit or adversely impact public health.

(C) Class R pharmacies shall be authorized to provide Class A, Class B, and Class C pharmacy services with a Class R permit. Class R pharmacies must apply for and hold the applicable pharmacy permit classification identified in section 338.220, RSMo, for any additional pharmacy services provided by the pharmacy. A Class J Shared services permit is not required for Class R pharmacies engaged in shared pharmacy services with the supervising pharmacy. If the Class R pharmacy is engaged in Class J shared services with another pharmacy, or has an arrangement to provide or receive Class J shared services with another pharmacy, the supervising pharmacy, the remote dispensing site, and all involved pharmacies must have a Class J shared services permit and comply with 20 CSR 2220-2.650.

(D) By the tenth day following each calendar quarter, Class R pharmacies must calculate the average number of prescriptions dispensed by the pharmacy per day during the previous calendar quarter, excluding immunizations given by protocol (e.g., January 10, April 10, July 10, October 10).

1. If the average number of prescriptions or medication orders dispensed by the pharmacy during the previous quarter exceeds one hundred fifty (150) prescriptions/medication orders per day, excluding immunizations given by protocol, the pharmacy must apply for a change of classification to add a Class A, B, or C permit classification within ten (10) days of discovery. Change of classification requests must be submitted on a form approved by the board with the applicable fee. Class R operations must cease once a Class A, B, or C permit is issued by the board.

2. Class R operations may resume if the daily average number of prescriptions dispensed by the pharmacy does not exceed one hundred fifty (150) prescriptions/medications orders during a calendar quarter (January 1–March 31, April 1–June 30, July 1-September 30, or October 1–December 31). The pharmacy's Class A, B, or C pharmacy classification must be surrendered to the board within five (5) days of resuming Class R operations.

(3) Supervising Pharmacies. Class R pharmacies must be under the supervision of a supervising pharmacy, as required by section 338.215, RSMo. The supervising pharmacy must ensure the Class R pharmacy is properly and safely operated in compliance with applicable state and federal law. Effective policies and procedures must be in place to ensure appropriate oversight of a Class R pharmacy at all times.

(A) The supervising pharmacy and Class R pharmacy must manually or electronically maintain a current and accurate written policy and procedure manual that complies with section 338.215, RSMo.

(B) The supervising pharmacy and Class R pharmacy must share a common database or have access to each other's prescription record-keeping system. The common database or shared system must allow real-time, online access to the patient's complete profile for both the supervising pharmacy and the Class R pharmacy.

(C) Supervising pharmacies must be located in Missouri and within fifty (50) miles of the supervised Class R pharmacy site, unless otherwise approved by the board. Requests to waive the location and mileage requirements must be submitted to the board in writing along with proof the Class R pharmacy will be sufficiently supported by the supervising pharmacy and that necessary personnel or supplies can be delivered to the Class R pharmacy within a reasonable period of time of an identifiable need. The board will also consider the factors identified in subsection (2)(B) of this rule when reviewing a waiver request.

(D) A Class R pharmacy must immediately cease operations if the supervising pharmacy and Class R pharmacy are no longer under common ownership, the supervising pharmacy is no longer eligible to supervise the Class R pharmacy, or the supervising pharmacy's Missouri pharmacy permit is not current and active. Class R operations may resume once the supervising pharmacy's permit returns to active or eligible status or common ownership is reestablished.

(4) Class R Standards of Operation. Except as otherwise authorized by law, Class R pharmacies must comply with all laws and regulations applicable to the pharmacy services provided by the Class R pharmacy, including, 20 CSR 2220-2.010.

(A) Class R pharmacies must be staffed by a current and active Missouri licensed pharmacist at least eight (8) hours a month. At a minimum, the pharmacist-in-charge (PIC) of the Class R pharmacy must visit the remote dispensing site weekly during the first month of operation to verify compliance and monthly thereafter. The date of the monthly PIC compliance visit must be documented in the pharmacy's records.

(B) Class R pharmacies must maintain a perpetual inventory for all controlled substances that is reconciled twice per month. The PIC must review the reconciliation for accuracy/discrepancies during the compliance visits required by subsection (4)(A).

(C) A prominent sign must be posted at the Class R pharmacy notifying patients that the remote dispensing site is supervised by the supervising pharmacy along with the supervising pharmacy's name, address, and telephone number.

(D) Intern pharmacists and qualified pharmacy technicians activities must be supervised by a Missouri-licensed pharmacist present at the Class R pharmacy or remotely supervised by a Missouri-licensed pharmacist located at the supervising pharmacy using technology that provides a continuous real-time audio and video link. The required technology must allow the supervising pharmacist to provide the personal assistance, direction, and approval needed to verify and ensure remote tasks are safely and properly performed. The supervising pharmacist must be employed by the supervising pharmacy, as required by section 338.215, RSMo, and must be competent to perform the services being supervised. A pharmacist cannot supervise more than two (2) Class R pharmacies at the same time.

(E) A Class R pharmacy may not be operated if the required supervision technology is unavailable or not in working order unless a pharmacist is onsite. The no pharmacist on duty sign required by 20 CSR 2220-2.010 must be posted in the event of a technology or system malfunction that requires the Class R pharmacy to cease operations.

(5) Medication Dispensing. Prescriptions/Medication orders may be prepared, dispensed, or compounded at a Class R pharmacy, as authorized by section 338.215, RSMo, and the rules of the board.

(A) The final contents and label of a prescription/medication order must be verified by a Missouri licensed pharmacist at the Class R pharmacy, or remotely verified by a Missouri licensed pharmacist located at the supervising pharmacy through the use of technology that includes bar coding and visual review of the medication contents and affixed label via remote video. The verifying pharmacist must be employed by the supervising pharmacy, as required by section 338.215, RSMo.

(B) Patient counseling must be provided for all new and refill prescriptions, unless refused by the patient. The required patient counseling must be provided by a Missouri licensed pharmacist at the Class R pharmacy or remotely provided by a Missouri licensed pharmacist at the supervising pharmacy via a HIPAA-compliant continuous real-time video and audio link, as authorized by section 338.215, RSMo. Medication may not be dispensed without a pharmacist physically present at the Class R pharmacy if the required counseling technology is not available or in working order. Remote patient counseling via technology may not be delegated to an intern pharmacist.

(C) Policies and procedures must be established to ensure appropriate pharmacist review of verbal prescription orders received by an intern pharmacist or qualified pharmacy technician at a Class R pharmacy when a pharmacist is not present.

(6) Adequate security and supervision must be maintained at all times to prevent unauthorized access to a Class R pharmacy and prevent medication theft and diversion.

(A) An alarm mechanism must be maintained that alerts the supervising pharmacy or the Class R pharmacist-in-charge in the event of unauthorized access to the remote dispensing site. Unauthorized access to a Class R pharmacy must be documented and reported to the board in writing within seven (7) days of discovery.

(B) Confidential records must be securely maintained to prevent unauthorized access and ensure secure data access and storage at all times.

(7) Record-Keeping.

(A) Except as otherwise provided by law, Class R pharmacies shall comply with all applicable record-keeping and documentation requirements of Chapter 338, RSMo, and the board's rules.

(B) Class R pharmacies must also maintain documentation of –

1. The number of prescriptions dispensed by the Class R pharmacy each calendar quarter; and

2. Proof that qualified pharmacy technicians and intern

pharmacists assisting at a Class R pharmacy have completed the experience, training, and competency assessment required by this rule.

(C) Records required by this rule must be manually or electronically maintained for two (2) years at the Class R pharmacy, or at the supervising pharmacy if the Class R pharmacy is no longer operating, and must be readily retrievable on request of the board or the board's authorized designee.

AUTHORITY: section 338.280, RSMo 2016, and sections 338.140 and 338.215, RSMo Supp. 2020. Original rule filed Sept. 3, 2020, effective March 30, 2021.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.215, RSMo 2020; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.685 Standards of Operation for a Class Q: Charitable Pharmacy

PURPOSE: This rule establishes licensing requirements and standards of operation for a Class Q Charitable Pharmacy.

(1) Definitions.

(A) "Charitable organization" – An organization qualified as a charitable organization pursuant to section 501(c)(3) of the *Internal Revenue Code*.

(B) "Charitable pharmacy" – A site in Missouri that is owned or operated by a charitable organization for purposes of providing pharmacy services to appropriately screened and qualified indigent patients. Class Q pharmacies may only provide services to or for qualified indigent patients.

(C) "Health care entity" – A hospital owned by the state of Missouri or any entity or organization that is licensed or certified by the state or federal government as a hospital, hospice facility, ambulatory surgical center, nursing home, long-term care facility, residential care facility, skilled nursing facility, mental/behavioral health care facility, or a habilitation center as defined by Chapter 630, RSMo, and that is required to maintain patient records by state or federal law.

(D) "Qualified indigent patient" – A patient of a charitable pharmacy that has been screened and approved by a charitable organization and deemed not to have sufficient funds to obtain needed medication based on the charitable organization's pre-established criteria.

(E) "Qualified intern pharmacist" – A currently licensed Missouri intern pharmacist who has completed employer approved training in the activities to be performed at a Class Q pharmacy and has an initial and, if applicable, annual documented assessment of competency.

(F) "Qualified pharmacy technician" – A currently registered Missouri pharmacy technician who –

1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies;

2. Has completed employer approved training in the activities to be performed at a Class Q pharmacy and has an initial and, if applicable, annual documented assessment of competency; and

3. Has assisted in the practice of pharmacy as a registered pharmacy technician in the state of Missouri for a minimum of one (1) year.

(2) Applications for a Class Q pharmacy must be submitted on a form approved by the board and must be renewed as provided by Chapter 338, RSMo, and 20 CSR 2220-2. No application fee is required (initial or renewal).

(3) Except as otherwise authorized by the board, Class Q pharmacies must comply with all laws and regulations applicable to the pharmacy services provided, including but not limited to 20 CSR 2220-2.010. Class Q pharmacies/applicants may petition the board to waive designated facility or pharmacy operational requirements not applicable to the Class Q pharmacy's operations. Waiver requests must be submitted in writing and must demonstrate how the permit holder will maintain patient safety and ensure appropriate patient care and pharmacy security, if approved. Controlled substances must be handled and dispensed in accordance with state and federal law.

(4) Class Q pharmacy services must be safely and accurately provided at all times, in compliance with state and federal law. If authorized by the pharmacist-in-charge, a qualified pharmacy technician or qualified intern pharmacist may assist in the practice of pharmacy at a Class Q pharmacy when a pharmacist is absent, with the exception of sterile compounding activities.

(A) Non-controlled medication may be dispensed or provided by a Class Q pharmacy when a pharmacist is absent if –

1. A pharmacist has previously verified the prescription/medication order contents and affixed label; or

2. Medication is provided to a healthcare provider for administration or delivery to the ultimate user as authorized by the healthcare provider's scope of practice, and bar code technology is used to verify the correct medication has been provided for the applicable patient. The healthcare provider must be notified that the medication has not been verified by a pharmacist prior to or on delivery.

(B) Patients or the patient's designee must be offered an opportunity to consult with a pharmacist as required by 20 CSR 2220-2.190. If the pharmacist is not present on site or unavailable to provide remote patient counseling, a written offer to counsel with a contact telephone number for a pharmacist must be supplied with the medication.

(C) If medication is dispensed or provided without a pharmacist present, a Missouri-licensed pharmacist designated by the pharmacist-in-charge must visit the Class Q pharmacy on a weekly basis to review the pharmacy's activities and records to ensure proper dispensing and compliance with this rule. The name of the reviewing pharmacist and review date must be documented and maintained in the pharmacy's records.

(D) The pharmacy's prescription records must identify any prescription/medication order dispensed without a pharmacist present.

(5) If authorized by the pharmacist-in-charge, a Missouri-licensed physician, dentist, physician assistant, or registered nurse may remove non-controlled medication from the pharmacy when a pharmacist is not at the Class Q location in an amount or volume needed to provide or administer to patients on the premises. Medication may only be removed pursuant to a valid order from a healthcare provider authorized to prescribe. The Class Q pharmacy must maintain a record of the distribution that includes the identity of the person removing the medication, the date removed, and the medication's identity, quantity, strength, and dosage form. A Missouri-licensed pharmacist must review the required documentation

on a weekly basis to ensure compliance with this rule. Controlled substances may not be removed or dispensed by a Class Q pharmacy unless a Missouri-licensed pharmacist is present and supervising.

(6) Donated Medication. A Class Q pharmacy may accept and dispense donated medication if –

(A) The medication is a non-controlled substance and is donated by a pharmacy, drug distributor, healthcare entity, or a healthcare provider who is licensed to prescribe. Donated medication cannot be accepted from a patient or a member of the public;

(B) The medication has not been previously dispensed to a patient and is donated in the original, sealed, and unopened manufacturer or unit of use packaging/container;

(C) The medication is not adulterated, misbranded, expired, outdated, subject to a recall, or otherwise not appropriate for patient use. A pharmacist must visually inspect all donated medication prior to placing the medication in active inventory to ensure the medication complies with the requirements of this rule;

(D) The donating entity/healthcare provider attests in writing that the medication has been stored in accordance with manufacturer or United States Pharmacopeia requirements/guidelines and all applicable state and federal law;

(E) The Class Q pharmacy maintains a record of donated medication that identifies the medication received, the donating entity/healthcare provider, the date received, and the medication's quantity, strength, lot number, dosage form, and expiration date; and

(F) The parties comply with all applicable state and federal laws.

(7) Policies and Procedures. Class Q pharmacies must maintain current and accurate policies and procedures governing pharmacy operations, including, but not limited to, policies/procedures for the following, if applicable:

(A) Accepting, dispensing, or filling prescriptions;

(B) Training pharmacy staff;

(C) Drug storage and security;

(D) Offering patient counseling;

(E) Contacting a pharmacist for consultation during the pharmacy's business operations or in the event of an emergency;

(F) If applicable, procedures for dispensing or providing medication in a pharmacist's absence pursuant to section (4) of this rule; including, documenting medication dispensed in the pharmacist's absence, reconciling medication inventory, notifying healthcare providers as required by subsection (4)(A), and documenting required healthcare provider notifications;

(G) Receiving, storing, dispensing, and disposal of donated medication;

(H) Granting, terminating, and monitoring authorized pharmacy access when a pharmacist is not present; and

(I) Reporting and handling of dispensing errors. The pharmacist-in-charge must be notified of a dispensing error within twenty-four (24) hours after the error is learned by pharmacy staff. Policies/procedures must include the manner of notification.

(8) Records. Records required by this rule must be maintained at the pharmacy for a minimum of two (2) years and must be readily retrievable and made available to the board or the board's authorized designee upon request.

(9) A Class Q pharmacy receiving a completed and labeled prescription from another pharmacy to provide to a qualified indigent patient is not considered to be shared services under 20 CSR 2220-2.650. For prescriptions received from another pharmacy –

(A) The Class Q pharmacy must maintain documentation of the prescription received, the name and address of the pharmacy providing the prescription, the date of receipt, the prescription number or unique identifier, and the patient's name;

(B) The Class Q pharmacy is responsible for ensuring compliance with all applicable patient counseling requirements;

(C) Prior to dispensing a prescription received from another pharmacy, a pharmacist must perform a drug utilization review with the patient information available at the Class Q pharmacy in compliance with 20 CSR 2220-2.195;

(D) If additional manipulation or compounding is required by the Class Q pharmacy, receipt of a prescription or medication order is required and the receiving pharmacy must dispense the product as their own prescription/order. All prescription, record keeping, compounding, and labeling requirements must be met; and

(E) Licensees shall comply with all applicable controlled substance laws and regulations, including but not limited to all applicable security and record keeping requirements.

AUTHORITY: sections 338.140, 338.210, 338.220, and 338.333, RSMo Supp. 2022, and sections 338.280 and 338.350, RSMo 2016. Original rule filed Jan. 26, 2021, effective July 30, 2021. Amended: Filed May 13, 2022, effective Nov. 30, 2022.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014, 2020; 338.280, RSMo 1951, amended 1971, 1981; 338.333, RSMo 1989, amended 2010, 2012, 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-2.700 Pharmacy Technician Registration

PURPOSE: This rule defines the requirements for pharmacy technician registration.

(1) A pharmacy technician is defined as any person who assumes a supportive role under the direct supervision and responsibility of a pharmacist and who is utilized according to written standards of the employer or the pharmacist-in-charge to perform routine functions that do not require the use of professional judgement in connection with the receiving, preparing, compounding, distribution, or dispensing of medications.

(A) No person shall assume the role of a pharmacy technician without first registering with the board in accordance with the requirements in section 338.013, RSMo and this rule. Nothing in this rule shall preclude the use of persons as pharmacy technicians on a temporary basis as long as the individual(s) is registered as or has applied to the board for registration as a technician in accordance with 338.013.1 and .2, RSMo.

(B) A person may be employed as a technician once a completed application and the required fee is received by the board. The board will provide either a registration certificate that shall be conspicuously displayed or a letter of disqualification preventing the applicant's employment within a pharmacy.

(C) Information required on the application shall include, but is not limited to –

1. The name, phone number, and residential address of the

applicant;

2. Full-time and part-time addresses where the applicant will be employed as a technician;

3. Information concerning the applicant's compliance with state and federal laws, as well as any violations that could be considered grounds for discipline as outlined in section 338.013.5, RSMo;

4. One (1) two-inch by two-inch (2" × 2") frontal view portrait photograph of applicant; and

5. Proof of fingerprinting as required by 20 CSR 2220-2.450.

(D) A copy of the application must be maintained by the applicant at the site(s) of employment during and until notice of registration or disqualification is received by the applicant and must be readily retrievable for review by the board of pharmacy or the board's representatives.

(2) Registered technicians as well as applicants for registration as a technician are responsible for informing the board in the case of a changed residential address. Any mail or communications returned to the board office marked unknown, incorrect address, and the like will not be mailed a second time until the correct address is provided.

(3) Registered technicians as well as applicants for registration as a technician shall inform the executive director of the board of any change in their employment address. The notification of an employment change must be provided in writing to the board no later than fifteen (15) days following the effective date of the change.

(4) Any person whose name appears on the board of pharmacy employment disqualification list shall be barred from employment as a pharmacy technician except as provided in section (5) of this rule.

(A) Information on the disqualification list shall include, at a minimum, the name and last known residential address of the person disqualified, as well as any previous registration number, the date on which the person's name was entered on the list and the date at which time the person will again become eligible for employment in a pharmacy. The board may place a person on the disqualification list for an indefinite period of time if the disqualified person fails to maintain a current mailing address with the board or fails to communicate with the board on a timely basis when contacted in writing by the board.

(B) Once the board has made a determination to place a person's name on the disqualification list, the board shall notify the person in writing by mailing the notification to the person's last known address. The disqualification notice shall include:

1. The name, address of residence and, if already registered as a technician, the registration number;

2. The reasons for being placed on the disqualification list;

3. The consequences of the person's name appearing on the list;

4. The time period of disqualification;

5. Any alternative restrictions or provisions for conditional employment, if provided by the board; and

6. The right to appeal the decision of the board as provided in Chapter 621, RSMo.

(5) Any person whose name appears on the disqualification list may be employed as a pharmacy technician subject to any restrictions or conditions ordered by the board. As an alternative to barring an individual from employment in a pharmacy, the board may consider restricted forms of employment or employment under special conditions for any person who has applied for or holds a registration as a pharmacy technician. Special conditions may include participation in the board's Well-Being Program, as provided in 20 CSR 2220-2.175. Any registered technician subject to restrictions or conditions who violates any portion of the restrictions or conditions may be further restricted in employment or have additional conditions placed on their registration. The board may also implement full disqualification on a registrant who has violated any restrictions or conditions.

(6) The letter of notice of intent to disqualify and the disqualification list shall be considered an open record of the board as well as any notice of appeal or litigation that pertains to the disqualification and/or conditional registration as a pharmacy technician.

AUTHORITY: sections 338.013 and 338.380, RSMo Supp. 2009, and section 338.140, RSMo 2000. This rule originally filed as 4 CSR 220-2.700. Original rule filed Aug. 21, 1998, effective Feb. 28, 1999. Amended: Filed Nov. 13, 2002, effective June 30, 2003. Moved to 20 CSR 2220-2.700, effective Aug. 28, 2006. Amended: Filed Aug. 18, 2009, effective March 30, 2010. ***

**Original authority: 338.013, RSMo 1997, 2004, 2009; 338.140, RSMo 1939, amended 1981, 1989, 1997; and 338.380, RSMo 2007.*

***Pursuant to Executive Order 21-09, 20 CSR 2220-2.700, section (1) was suspended from March 20, 2020 through December 31, 2021.*

20 CSR 2220-2.710 Pharmacy Technician and Intern Pharmacist Supervision

PURPOSE: This rule defines the required supervision for pharmacy technicians and intern pharmacists.

(1) Pharmacy technicians and intern pharmacists may assist a pharmacist in the practice of pharmacy as authorized by Chapter 338, RSMo, and the rules of the board, provided delegated tasks are performed under the direct supervision of a pharmacist. Direct supervision means supervision by a Missouri licensed pharmacist who is readily and immediately available at all times the delegated tasks are being performed and who provides personal assistance, direction, and approval throughout the time the delegated tasks are being performed. "Readily and immediately available" means the pharmacist and pharmacy technician(s) or intern pharmacists are on the same physical premises, or if not, technology is used to communicate with and monitor the pharmacy technician and intern pharmacist, as authorized in section (2).

(2) Use of Technology. Except as otherwise provided by law or regulation, technology may be used to directly supervise a pharmacy technician and intern pharmacist, provided:

(A) Sufficient technology is available to allow communication between the pharmacist and the pharmacy technician or intern pharmacist in a manner that is sufficient to provide the personal assistance, direction, and approval required to verify and ensure delegated tasks are safely and properly performed. Technicians and intern pharmacists may not be supervised as authorized by this subsection if the required technology is not operating or available;

(B) All applicable state and federal laws are fully observed, including, but not limited to, all applicable privacy and

confidentiality laws;

(C) The pharmacy technician or intern pharmacist has completed employer approved training in the activities performed and has an initial and annual documented assessment of competency. Documentation of the completed training and competency assessment must be maintained in the pharmacy's records for a minimum of two (2) years and provided to the board or the board's designee upon request; and

(D) The supervising pharmacist and the permit holder must maintain a sufficient audit trail of prescription/medication order data entry and modifications to a patient record performed by a pharmacy technician or intern pharmacist being supervised as authorized by this subsection. The record must include the identity of the pharmacy technician or intern pharmacist performing the data entry or modification and must be maintained in the pharmacy's records for a minimum of five (5) years.

(3) The supervising pharmacist and permit holder shall retain responsibility for activities delegated to a pharmacy technician or intern pharmacist.

(4) Nothing in this rule shall override the provisions of 20 CSR 2220-2.010.

(5) Unless otherwise provided by law or court of competent jurisdiction, the provisions of this rule are only applicable to pharmacy services under the jurisdiction of the board and are not applicable to hospital pharmacy services under the jurisdiction of the Missouri Department of Health and Senior Services pursuant to Chapter 197, RSMo.

AUTHORITY: sections 338.010 and 338.140, RSMo Supp. 2019, and sections 338.013, 338.035, and 338.280, RSMo 2016. Original rule filed Feb. 7, 2020, effective Aug. 30, 2020. Emergency rule filed June 5, 2020, effective June 19, 2020, expired Sept. 1, 2020.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019; 338.013, RSMo 1997, amended 2004, 2009; 338.035, RSMo 1990, amended 1993, 1995, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.725 Remote Data Entry

PURPOSE: This rule authorizes and establishes requirements for remote data entry sites.

(1) Definitions.

(A) "Remote Data Entry Sites" – A remote site located in a U.S. state or territory that is operated by a Missouri licensed pharmacy and used by a Missouri licensed or registered pharmacy technician or intern pharmacist to electronically perform non-dispensing data entry functions, including, but not limited to, obtaining, entering, validating, or processing patient information or data.

(B) "Supervising Pharmacy" – A Missouri licensed pharmacy that is physically located in Missouri and responsible for operating a remote data entry site.

(2) Licensing.

(A) "Remote Data Entry Sites" – A permit is not required for a remote data entry site. The site shall be deemed part of and operating under the supervising pharmacy's permit. The supervising pharmacy must maintain an address listing of all remote data entry sites in operation which must be made immediately available upon request of the board or the board's authorized designee.

(3) Remote data entry sites must be safely operated in compliance with applicable state and federal law. The supervising pharmacy is responsible for all pharmacy operations at the remote data entry site. No medication or medical device may be located at or dispensed from a remote data entry site.

(A) Adequate security and supervision must be maintained at all times to prevent unauthorized access to the remote data entry site and equipment. Confidential records must be securely maintained to prevent unauthorized access to, and unauthorized storage/transfer of, confidential information. Any breach in the security of the remote data entry site equipment or confidential records must be documented and reported to the board in writing within seven (7) days of the breach. Paper patient or prescription records may not be generated, located, or maintained at a remote data entry site.

(B) Except as otherwise provided by state and federal requirements, the remote data entry site and the supervising pharmacy must share a common database or prescription record-keeping system that allows real-time, online access to relevant patient profile information by both the supervising pharmacy and the remote site. The identity of the pharmacy technician or intern pharmacist responsible for remotely entering, validating, or modifying data at a remote data entry site must be electronically documented/recorded in the pharmacy's records and maintained for a minimum of five (5) years.

(C) Pharmacy technicians and intern pharmacists operating at a remote data entry site must be competent in the duties performed. At a minimum, technicians and intern pharmacists must have completed employer approved training in the activities performed remotely and must have an initial and, if applicable, annual documented assessment of competency. Documentation of the completed training and competency assessment must be maintained in the pharmacy's records for a minimum of two (2) years and provided to the board or the board's designee upon request.

(D) A sufficient mechanism must be in place to allow communication between the supervising pharmacist and pharmacy technician or intern pharmacist when needed. A pharmacist must be available to respond to technician/intern pharmacist questions at all times a remote data entry site is in operation and must provide the personal assistance, direction, and approval required to verify and ensure delegated tasks are safely and properly performed. Non-dispensing data entry functions may not be performed by a pharmacy technician or intern pharmacist at a remote data entry site if the required real-time communication mechanism is not operating or available.

(E) Remote data entry sites may be inspected by the board as authorized by law. Notification by the inspector will be provided to the supervising pharmacy a minimum of seventy-two (72) hours ahead of the scheduled inspection. The supervising pharmacy permit holder must arrange for a designated representative to be present that is not a resident of the location under inspection.

(4) Policies and Procedures. The supervising pharmacy must establish written policies and procedures governing all aspects of operation of a remote data entry site that are reviewed annually by the pharmacist-in-charge. At a minimum, policies and procedures must include authorized technician and

intern pharmacist activities, site security procedures and requirements, reporting security breaches, quality assurance review procedures, and staff education/training. The annual policy and procedure review date must be documented in the pharmacy's records.

AUTHORITY: sections 338.010, 338.035, and 338.140, RSMo Supp. 2021, and sections 338.013 and 338.280, RSMo 2016. Original rule filed Feb. 7, 2020, effective Aug. 30, 2020. Emergency rule filed June 5, 2020, effective June 19, 2020, expired Sept. 1, 2020. Amended: Filed Nov. 2, 2021, effective May 30, 2022.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019, 2021; 338.013, RSMo 1997, amended 2004, 2009; 338.035, RSMo 1990, amended 1993, 1995, 2007, 2020; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.800 Vacuum Tube Drug Delivery System

PURPOSE: This rule defines the minimum standards for a vacuum tube drug delivery system utilized in licensed pharmacies.

(1) Vacuum tube systems are for use in the delivery of drugs to the patient or his/her agent.

(A) Any drug delivery system that utilizes a vacuum tube to deliver drugs outside of a licensed pharmacy must be designed and engineered in such a way as to ensure security of all drugs and that drugs are delivered correctly and efficiently to the intended recipient.

(B) Only systems that are dedicated for the delivery of drugs from a location within a licensed pharmacy to another location specific for drug delivery and are not connected, combined or attached to other systems shall be used. Multiple or switchable stations where the delivery of drugs could occur at more than one destination outside of the pharmacy are prohibited.

1. When the pharmacy is closed or there is no pharmacist on duty, the vacuum tube system must be turned off and no drugs shall be delivered to consumers during these time periods.

(C) Any pharmacy, which cannot maintain a direct and identifiable line of sight with the consumer, must maintain a video camera and audio system to provide for effective communication between pharmacy personnel and consumers. It must be a system that will allow for the appropriate exchange of oral as well as written communications to facilitate patient counseling and other matters involved in the correct transaction or provision of drugs.

1. Video monitors used for the proper identification of persons receiving prescription drugs shall be a minimum of twelve inches (12") wide.

2. Both the video monitor and the audio system must be in good working order or operations utilizing the vacuum tube system shall cease until appropriate corrections or repairs are made to the system(s).

3. Backlighting or other factors that may inhibit video or audio performance must be taken into account when using such systems to identify recipients of prescription drugs. Positive identification of recipients must be made before any drug is delivered.

(2) Any vacuum tube delivery system already installed in a pharmacy prior to September 1, 1998, will not be required to comply with this rule; except that, should the vacuum tube delivery system or any part thereof require replacement, change, or upgrading after September 1, 1998, the system or any part of the system being replaced, changed, or upgraded shall comply with the minimum standards set forth in this rule. This exemption does not relieve a pharmacy of its duty to maintain adequate security measures as required by Chapter 195, RSMo, 19 CSR 30-1, or the rules of the board; nor does it relieve pharmacists from their duty to provide patient counseling as required by 20 CSR 2220-2.190.

AUTHORITY: section 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-2.800. Original rule filed Aug. 21, 1998, effective Feb. 28, 1999. Moved to 20 CSR 2220-2.800, effective Aug. 28, 2006. Amended: Filed May 13, 2019, effective Nov. 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019 and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.900 Class N: Health Care Facility Automated Dispensing Systems

PURPOSE: This rule establishes licensing standards and requirements for the use of Class N automated dispensing systems (Health Care Facility).

(1) Definitions.

(A) "Class N: Automated dispensing system" (ADS) – An automated system located within a licensed health care facility used to dispense medication for resident patients of the facility pursuant to a patient-specific prescription or a medication order as defined by Chapter 338, RSMo, or a prescription drug order as defined by 20 CSR 2220-2.140. An automated dispensing system does not include an automated system used for compounding medication, a Class O automated dispensing system, or an automated filling system governed by 20 CSR 2220-2.950.

(B) "Electronic verification system" – An electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system process used to verify and ensure medication has been properly stocked, restocked, loaded, filled, dispensed, or labeled.

(C) "Licensed health care facility" – A health care facility licensed by or operated by the state of Missouri, or otherwise authorized by the state, to administer health care to resident patients in the ordinary course of business or professional practice.

(D) "Med pak" – A patient med pak as defined by 20 CSR 2220-2.145.

(2) Licensing. Applicants for a Class N (ADS) permit classification must file an application on a form approved by the board with the applicable fee, and submit proof that the proposed Class N ADS location qualifies as a licensed health care facility, as defined by this rule.

(A) A Class N ADS permit will be issued for the health care facility address designated on the application, and may be used to operate all Class N ADSs located at the board approved address. A Class N ADS must be located indoors at the permitted health care facility address and may not be located outside of the health care facility.

(B) The appropriate pharmacy permit classification is required for any pharmacy activities under the board's jurisdiction that occur at the Class N ADS site other than dispensing from an automated dispensing system. Class N ADS pharmacies must comply with all requirements applicable to

any additional pharmacy permit classifications held by the pharmacy, including but not limited to all applicable security and staff supervision requirements. A Class J pharmacy permit is required for shared service activities, as provided in 20 CSR 2220-2.650.

(C) A Class N ADS permit is not required for automated dispensing systems used solely to provide medication for immediate administration by health care facility staff to resident patients in an emergency situation, as allowed by law or the health care facility's licensing agency.

(3) System requirements. A Class N ADS must be maintained in good working order and in a clean and sanitary manner. If applicable, a Class N ADS must be cleaned and disinfected on a regular basis using appropriate materials and agents.

(A) A Class N ADS must be validated by a properly qualified board licensee or appropriately supervised board registrant designated by the pharmacy to ensure the system is functioning properly prior to first use and prior to restarting the system after an unanticipated system shutdown or interruption. Additional validation must occur if any modification to the automated dispensing system occurs that changes or alters the dispensing or electronic verification process.

(B) Medication must be stored and maintained in a thermostatically controlled area within temperature and humidity requirements as provided in the Food and Drug Administration approved drug product labeling or the United States Pharmacopeia (USP).

(C) At a minimum, temperatures in drug storage areas of the ADS must be recorded and reviewed daily. Alternatively, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings that promptly alerts pharmacy staff when temperatures are outside of the required range and provides the amount of variance.

(D) An ongoing and documented quality assurance program must be established to monitor the performance of the automated dispensing system. The quality assurance program must include procedures for handling and reporting dispensing errors, system malfunctions, and other compliance concerns.

(E) A pharmacist must reconcile a sample size of medication dispensed/removed from a Class N ADS on a quarterly basis to verify authorization for dispensing. The required sample size must be identified in the pharmacy's policies and procedures. Proof of compliance with this subsection and the review date(s) must be maintained and documented in the pharmacy's records.

(4) Standards of operation. A Class N ADS must be safely and properly operated at all times in compliance with applicable state and federal laws, including but not limited to all applicable controlled substance laws.

(A) A Class N ADS may only be used in settings that ensure prescriptions and medication/drug orders are reviewed by a pharmacist. Only staff of the licensed health care facility may remove or obtain medications from a Class N ADS for patient use. Patients may not obtain medication directly from the automated dispensing system.

(B) Medication may only be dispensed by a Class N ADS pursuant to a valid prescription or medication/drug order. A prospective drug utilization review must be conducted for initial and changed prescriptions and medication/drug orders, as required by 20 CSR 2220-2.195. Policies and procedures must be in place for reviewing medication dispensing for compliance with this subsection, including but not limited to policies and procedures for terminating discontinued prescriptions and medication/drug orders and as needed prescriptions and medication/drug orders to prevent unauthorized dispensing.

(C) A pharmacist must control all operations of the ADS and approve the release of the initial dose, except in cases of emergency dispensing for immediate administration to a patient as authorized by law. Subsequent doses from an approved prescription or medication/drug order may be removed from the ADS by health care staff in accordance with the pharmacy's policies and procedures, provided a pharmacist must approve the release of subsequent dose(s) if any change in the prescription or medication/drug order occurs. Subsequent doses of patient-specific labeled prescriptions must comply with subsection (4)(D) of this rule.

(D) For ADSs that dispense a patient-specific labeled prescription or medication/drug order, pharmacist verification of the final drug product and label may be satisfied if –

1. A pharmacist reviews and verifies the prescription or medication/drug order and the patient information used to initiate the dispensing process prior to dispensing;

2. The entire dispensing process is fully automated from the time the process is initiated until a completed, sealed, and properly labeled medication container is produced that is ready for dispensing. Required labels must be affixed to the container prior to release of the medication from the automated dispensing system. No manual manipulation of the prescription container or label may occur after the medication is released; and

3. An electronic verification system is used to ensure the correct label has been affixed and the correct medication and medication strength, dosage form, and quantity have been dispensed.

(E) Labeled prescription containers provided to patients must be labeled in accordance with applicable statutory and regulatory requirements, and must contain the name, address, and telephone number of the Class N ADS permit holder. Med paks dispensed by a Class N ADS must comply with all applicable provisions of 20 CSR 2220-2.145, regardless if given to the patient.

(F) In addition to 20 CSR 2220-2.080 and other prescription record-keeping requirements, the following information must be documented and readily retrievable for all prescriptions and medication/drug orders removed from the system:

1. The patient's name or other unique identifier;

2. The date and time the medication is removed;

3. The medication, dosage strength, and quantity removed; and

4. The identity or other unique identifier of the authorized health care staff member removing the medication.

(5) Supervision. A Class N ADS must be supervised by a Missouri-licensed pharmacist who is readily accessible physically or electronically to monitor system activities and respond to inquiries or requests (e.g., on call). Electronic technology must allow the pharmacist to adequately monitor and supervise Class N ADS operations. The pharmacist supervision required by this section may not be delegated to an intern pharmacist.

(A) If applicable, a two- (2-) way audio communication system must be in place to allow pharmacy technicians or intern pharmacists present at the Class N ADS pharmacy to effectively communicate with the supervising pharmacist. The Class N ADS may not be operated if the electronic or communication technology required by this section is unavailable or not in working order unless a pharmacist is on-site.

(6) Stocking/restocking. Medication must be securely stocked, loaded, and reloaded in a Class N ADS in a manner that protects against theft and diversion, and in compliance with 20 CSR 2220-2.010.

(A) Only board licensees or registrants may stock, load, or restock a Class N ADS, as authorized by the pharmacy's policies and procedures.

(B) A pharmacist must physically verify that medication has been properly stocked, restocked, and loaded into a Class N ADS. Alternatively, an electronic verification system may be used to verify that medication or medication containers have been properly stocked, restocked, and loaded into the device, if no manual intervention with the medication or medication container after the electronic verification occurs other than health care staff retrieving medication or medication being removed by authorized pharmacy staff for return/destruction.

(C) If authorized by a pharmacist, intern pharmacists, or pharmacy technicians may stock, restock, or load manufacturer unit of use packages and repacked containers previously verified by a pharmacist into a Class N ADS without a pharmacist present or additional pharmacist verification if an electronic verification system is used to verify the manufacturer unit of use packages and repacked containers have been correctly stocked, restocked, or loaded. No manual intervention with the manufacturer unit of use package or repacked container may occur after the electronic verification required by this subsection, other than removing the manufacturer unit of use package or repacked containers by authorized health care facility staff for dispensing or return/destruction.

(D) Return-to-stock medication may be returned and reused as authorized by 20 CSR 2220-3.040 or 20 CSR 2220-2.145 governing multi-med dispensing. No medication shall be returned directly to the Class N ADS for reissue or reuse by a person not licensed or registered by the Board of Pharmacy.

(E) The following documentation must be maintained and readily retrievable:

1. The name, strength, and quantity of the medication stocked, loaded, restocked, or removed from the ADS system;

2. The date and time medication is stocked, loaded, restocked, or removed from the ADS system;

3. The identity of individuals stocking, loading, restocking, or removing medication in the ADS system; and

4. The identity of the pharmacist responsible for verifying the contents of any repacked containers stocked, restocked, or loaded into the ADS system, if applicable.

(7) Security. Adequate security and supervision must be maintained at all times to prevent medication theft and diversion and unauthorized access to or use of the Class N ADS. A Class N ADS must also comply with all security provisions of 20 CSR 2220-2.010. Confidential records and Class N data must be securely maintained to prevent unauthorized access to, and unauthorized storage/transfer of, confidential information.

(A) A Class N ADS must be securely placed, locked, and maintained inside the physical building of the licensed health care facility in a manner that prevents theft, diversion, and unauthorized access or medication removal.

(B) A Class N ADS must have an alarm mechanism that promptly alerts a designated member of the pharmacy's staff in the event of a security breach or unauthorized access to the system.

(C) Authorized access to the Class N ADS must be defined in the pharmacy's policies and procedures. The permit holder must be able to stop or change access to the Class N ADS as deemed necessary or appropriate.

(D) A perpetual inventory must be maintained for each Class N ADS that stocks controlled substances that is reconciled by pharmacy staff on a monthly basis.

(E) Class N ADS permit holders must maintain current policies and procedures for handling and investigating confirmed or suspected security breaches and medication losses or diversion, including but not limited to an escalation policy/procedure for addressing inventory discrepancies and policies/procedures for terminating system operations in the event of a security breach, inventory discrepancy, suspected loss/diversion, or unauthorized access to or loss of patient confidential information.

(F) Security breaches of the Class N ADS must be immediately investigated. Use/operation of the Class N ADS must immediately cease until the security breach has been rectified and proper security is restored. Any security breach of the Class N ADS must be documented and reported to the board in writing within three (3) business days of discovery.

(G) Any confirmed or suspected medication diversion/theft must be immediately investigated. Medication diversion/theft must be reported to the board in writing within three (3) business days of discovery.

(8) Policies and procedures. Class N ADS permit holders must maintain current and accurate written policies and procedures governing all aspects of Class N ADS activities, including but not limited to –

(A) Staff education and training;

(B) Maintaining the Class N ADS and the accompanying electronic verification process in good working order;

(C) Maintaining and protecting system data and confidential information;

(D) Granting, restricting, or terminating Class N ADS system access;

(E) Filling, stocking, restocking, and loading the Class N ADS;

(F) Removing expired, adulterated, misbranded, or recalled medication;

(G) Temperature monitoring and documentation;

(H) Prescription processing, verification, and recordkeeping, including handling/termination of discontinued prescriptions and medication/drug orders and as-needed prescriptions and medication/drug orders to prevent unauthorized dispensing;

(I) Patient counseling, if applicable;

(J) Ensuring cleanliness and sanitary operation of the device and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(K) Emergency response procedures, including but not limited to addressing power outages and terminating system operations;

(L) Monitoring medication inventory to prevent diversion, theft, or loss, including an escalation policy/procedure for addressing inventory discrepancies;

(M) Security requirements, including policies/procedures for authorizing Class N ADS system access and terminating Class N ADS system operations in the event of a security breach;

(N) Handling and investigating inventory discrepancies, suspected loss/diversion, or unauthorized access to or loss of patient confidential information;

(O) Receiving, handling, documenting, and investigating alarm notifications/alerts in the event of a security breach or unauthorized access to the Class N ADS, as referenced in section (7);

(P) Conducting routine and preventive system validation and maintenance;

(Q) Quality assurance;

(R) Handling, investigation, and reporting dispensing errors;
(S) Recordkeeping; and
(T) Data retention and retrieval.

(9) Records.

(A) Class N permit holders must maintain readily retrievable records of all Class N ADS transactions, including but not limited to all prescriptions and medication/drug orders processed and/or dispensed by the Class N ADS and records of all medication stocked in or removed from the Class N ADS.

(B) Prescriptions and medication/drug orders dispensed from a Class N ADS must be separately identifiable in the pharmacy's prescription records and individually retrievable from other prescriptions and medication/drug orders dispensed by the pharmacy. This requirement also applies to any Class J pharmacy dispensing prescriptions or medication/drug orders via a Class N ADS.

(C) Except as otherwise provided by this rule or other applicable law, all records required by this rule must be maintained a minimum of two (2) years and readily retrievable on request of the board or a board-authorized designee. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from the board or the board's authorized designee, or by making a computer terminal available to the inspector for immediate use to review the records requested. Records not maintained at a pharmacy must be produced within three (3) business days of a board request.

AUTHORITY: sections 338.140, 338.210, and 338.220, RSMo Supp. 2023, and section 338.280, RSMo 2016. This rule originally filed as 4 CSR 220-2.900. Original rule filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed Feb. 18, 2003, effective Sept. 30, 2003. Moved to 20 CSR 2220-2.900, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007. Amended: Filed Sept. 6, 2023, effective March 30, 2024.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014, 2020; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.910 Class O: Automated Dispensing Systems (Ambulatory Care)

PURPOSE: This rule establishes licensing standards and requirements for Class O: Automated Dispensing Systems (Ambulatory Care).

(1) Definitions.

(A) "Ambulatory prescription dispensing system" – A Class O automated dispensing system (Class O ADS) used to process, verify, fill, label, and dispense a completed prescription/medication order for patient retrieval from the system using an electronic verification system.

(B) "Class O automated dispensing system" – A pharmacy license classification which allows the use of an ambulatory prescription dispensing system or a prescription pick-up system as defined by this rule at a specific location. A Class O ADS does not include an automated system used for compounding medication, a Class N automated dispensing system, or an automated filling system governed by 20 CSR 2220-2.950.

(C) "Electronic verification system" – An electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system process used to verify and ensure medication/prescriptions have been properly stocked, restocked, loaded, filled, dispensed, or labeled.

(D) "Prescription pick-up system" – A Class O ADS that allows a patient to obtain a filled, labeled, and pharmacist-verified prescription/medication order placed in the system by or on behalf of a Missouri-licensed pharmacy for patient retrieval. A prescription pick-up system does not include a vacuum tube drug delivery system identified in 20 CSR 2220-2.800.

(E) "Supervising pharmacist" – A Missouri-licensed pharmacist designated to supervise a Class O ADS while the system is in operation.

(2) Licensing. Applicants for a Class O ADS pharmacy permit classification must file an application on a form approved by the board and pay the applicable fee. A pharmacy Change of Classification application is required for currently licensed Missouri pharmacies opting to add a Class O ADS classification to their existing Missouri pharmacy permit. Application fees to add or obtain a Class O ADS pharmacy permit shall be waived for Class N ADS permit holders licensed on the effective date of this rule for a period of six (6) months from this rule's effective date.

(A) A Class O ADS permit may be used to operate all Class O ADSs located at the address designated on the permit. A Class O ADS may only be used by the permit holder, and may not be used to dispense prescriptions/medication orders for multiple pharmacies.

(B) The appropriate pharmacy permit classification is required for any pharmacy activities under the board's jurisdiction that occur at the Class O ADS site other than operating the Class O ADS. Class O ADS pharmacies must comply with all requirements applicable to any additional pharmacy permit classifications held by the pharmacy, including but not limited to all applicable security and staff supervision requirements. A Class J pharmacy permit is required for shared service activities, as provided in 20 CSR 2220-2.650.

(C) To be eligible for licensure, a Class O ADS must be located within the permitted address of a Missouri-licensed pharmacy where pharmacy services other than Class J Shared services, Class I Consultant services, or Class O ADS services are provided, or at an indoor location where health care services are regularly provided by a licensed health care provider at the same location. A Class O ADS must be located at an address recognized by the United States Postal Service and may not be located outside of a physical structure.

(D) Applicants may petition the board in writing to approve a Class O ADS at an alternative location to increase patient access to medication in an area where access to an ambulatory/community pharmacy is limited. Petition requests must include documentation or evidence demonstrating how the proposed Class O ADS location will expand patient access to medication and promote public health. The board will consider the following factors when determining petition requests:

1. The availability of pharmacy services in the proposed Class O ADS pharmacy area;
2. Benefits or risks to patient care;
3. Policies/procedures for ensuring adequate security;
4. The permit holder's ability to promptly access the Class O ADS in the event of an emergency, which shall be no more than thirty (30) minutes;
5. The applicant's experience and compliance history; and
6. Any other factor that may benefit or adversely impact public health.

(3) System requirements. A Class O ADS must be maintained

in good working order and in a clean and sanitary manner. If applicable, a Class O ADS must be cleaned and disinfected on a regular basis using appropriate materials and agents.

(A) A sign must be conspicuously posted or electronically displayed on the Class O ADS that clearly identifies the permit holder's name, address, the system's hours of operation, and a telephone number for contacting the pharmacy during operational hours.

(B) A Missouri-licensed pharmacist must be capable of being physically present at the approved Class O ADS location within thirty (30) minutes in the event of an emergency or other system malfunction.

(C) A video surveillance system must be in place that allows the pharmacy to physically view the Class O ADS and the Class O ADS site at all times. A video surveillance system is not required if a pharmacist is present on-site and able to view the Class O ADS at all times the system is accessible to the public.

(D) Medication must be stored and maintained in a thermostatically controlled area within temperature and humidity requirements as provided in the Food and Drug Administration approved drug product labeling or the United States Pharmacopeia (USP).

(E) At a minimum, temperatures in drug storage areas of the Class O ADS must be recorded and reviewed daily. Alternatively, a continuous temperature monitoring system may be used to comply with this subsection, if the system maintains ongoing documentation of temperature recordings that promptly alerts pharmacy staff when temperatures are outside of the required range and provides the amount of variance.

(F) The Class O ADS system must use an electronic verification system to electronically verify and ensure prescriptions/medication orders are properly dispensed to the correct patient. The electronic verification system(s) must be validated by a properly qualified board licensee or appropriately supervised board registrant designated by the pharmacy to ensure the system is functioning properly prior to first use and prior to restarting the system after an unanticipated system shutdown or interruption. Additional validation must occur if any modification to the Class O ADS occurs that changes or alters the dispensing or electronic verification process. Validation dates and results must be documented in writing and readily retrievable.

(G) The Class O ADS permit holder must regularly review system operations to ensure proper functioning. At a minimum, a Missouri-licensed pharmacist must visit and review Class O ADS operations weekly during the first month of system operations and monthly thereafter. The dates of the required weekly and monthly visits/reviews and the identity of the designated pharmacist must be documented and readily retrievable at the request of the board or the board's authorized designee. The permit holder shall remain responsible for Class O ADS services and ensuring proper functioning.

(H) An ongoing and documented quality assurance program must be established to monitor the performance of the Class O ADS. The quality assurance program must include procedures for handling and reporting dispensing errors, system malfunctions, and other compliance concerns.

(I) Notification of any dispensing error involving a Class O ADS that is dispensed to the patient must be submitted electronically or in writing to the board within ten (10) days of discovery. The required notification must include the date of the incident, patient name, description of the error, the applicable prescription/medication order number or unique identifier, and any corrective action taken.

(4) Standards of operation. A Class O ADS must be safely and properly operated at all times in compliance with applicable state and federal laws, including but not limited to all applicable controlled substance laws. Medication must be accurately dispensed and labeled.

(A) Medication may only be dispensed by a Class O ADS pursuant to a valid patient-specific prescription or medication order. A Class O ADS may not be used to dispense prescriptions/medication for multiple pharmacies.

(B) The Class O ADS must be supervised at all times it is in operation by a Missouri-licensed pharmacist who is either physically present at the Class O ADS site or who is supervising via an electronic system that allows the pharmacist to adequately view the Class O ADS and supervise all Class O ADS activities. The required pharmacist supervision may not be delegated to an intern pharmacist.

1. The supervising pharmacist must maintain full operational control over the Class O ADS whenever the Class O ADS is in operation, and must be able to terminate or suspend Class O ADS operations when deemed necessary or appropriate.

2. The required electronic system must provide a continuous real-time video link to allow the supervising pharmacist to see the entire Class O ADS site. A two- (2-) way communication mechanism must also be available that allows communication between the supervising pharmacist and any technicians or intern pharmacists present on-site. Medication may not be dispensed and the Class O ADS may not be operated if the required video link and audio communication are not fully functioning.

3. A supervising pharmacist may not supervise more than two (2) Class O ADSs at a time. The identity of the supervising pharmacist must be documented and maintained in the supervising pharmacy's records. Licensees may request a waiver of the supervision limit. The board will consider the factors in subsection (2)(D) when determining waiver requests.

(C) For Class O ADS prescription pick-up systems, only filled and labeled prescriptions that have been verified by a pharmacist may be loaded in or dispensed from the Class O ADS prescription pick-up system, except as otherwise authorized by law. The entire dispensing process must be fully automated after the prescription/medication order is loaded into the Class O prescription pick-up system. No manual manipulation of the prescription/medication order or the affixed label may occur after the prescription/medication order is stocked, restocked, or loaded in the Class O ADS prescription pick-up system.

(D) For Class O ADS ambulatory prescription dispensing systems, the entire prescription/medication order filling, dispensing, and labeling process must be automated and the required prescription/medication label must be affixed by the Class O ADS ambulatory prescription dispensing system prior to dispensing from the Class O ADS ambulatory prescription dispensing system. No manual manipulation of the prescription/medication order or the affixed label may occur after the automated filling process is initiated.

(E) Medication may not be dispensed via a Class O ADS if the patient or the patient's authorized designee requests not to use the Class O ADS.

(5) Patient counseling. An offer to counsel must be made to the patient or the patient's authorized representative prior to a prescription or medication order being dispensed from a Class O ADS, except as otherwise required by law for Class R remote dispensing site pharmacies. The offer to counsel may be made verbally by authorized pharmacy staff or made electronically via the Class O ADS.

(A) Adequate space and equipment must be available to confidentially counsel patients. Live, real-time patient counseling

must be provided if counseling is requested by the patient or otherwise required. If a pharmacist is not present on-site, two-(2-) way video and audio technology must be available that allows the pharmacist and patient to both view and communicate with each other. Medication may not be dispensed if the required video and audio technology is not fully functioning.

(B) Video monitors/screens used for patient counseling or communication must be a minimum of twelve inch (12") wide diagonally. Backlighting or other factors that may inhibit video performance must be taken into account when using video technology to counsel/communicate with patients.

(C) A sign must be conspicuously posted or continuously displayed electronically on the Class O ADS informing patients that a pharmacist will provide counseling either in-person or via the video/audio system on request. The sign must include clear instructions for requesting counseling and must be easily viewed and readable by the public.

(6) Stocking/restocking. Medication must be securely stocked, loaded, and reloaded in a Class O ADS in a manner that protects against theft or diversion, and in compliance with 20 CSR 2220-2.010.

(A) Only board licensees or registrants may stock, load, or restock a Class O ADS, as authorized by the supervising pharmacy's policies and procedures.

(B) For Class O ADS prescription pick-up systems, a pharmacist must physically verify that prescriptions/medication orders have been properly loaded into the Class O ADS prescription pick-up system. The identity of the verifying pharmacist must be documented and maintained in the pharmacy's records. Alternatively, an electronic verification system may be used to verify that prescriptions/medication orders have been properly loaded into the Class O ADS prescription pick-up system, if no manual intervention with the prescription/medication order occurs after the electronic verification is completed. If authorized by a pharmacist, intern pharmacists or pharmacy technicians may load a Class O ADS prescription pick-up system without a pharmacist present or additional pharmacist verification if –

1. An electronic verification system is used to verify the prescription/medication order has been properly loaded into the ADS system;

2. No manual intervention with the prescription/medication order occurs after the electronic verification required by this subsection, other than removing the prescription/medication order by authorized pharmacy staff for return/destruction; and

3. The electronic verification system has been validated and revalidated as required by subsection (3)(F). Validation dates and results must be documented in writing and readily retrievable.

(C) For Class O ADS ambulatory prescription dispensing systems, an electronic verification system must be used to verify that medication or medication containers have been properly stocked, restocked, and loaded into the Class O ADS ambulatory prescription dispensing system. If authorized by a pharmacist, intern pharmacists or pharmacy technicians may stock, restock, or load manufacturer unit of use packages and repacked containers previously verified by a pharmacist into a Class O ADS ambulatory prescription dispensing system without a pharmacist present or additional pharmacist verification if –

1. An electronic verification system is used to verify the medication has been correctly stocked, restocked, or loaded;

2. No manual intervention with the manufacturer unit of use package or repacked container occurs after the required electronic verification required by this subsection occurs, other than removing the manufacturer unit of use package or repacked container by authorized pharmacy staff for return/destruction; and

3. The electronic verification system has been validated and revalidated as required by subsection (3)(F). Validation dates and results must be documented in writing and readily retrievable.

(D) Return-to-stock medication may be returned and reused as authorized by 20 CSR 2220-3.040 or 20 CSR 2220-2.145 governing multi-med dispensing. No medication shall be returned directly to a Class O ADS for reissue or reuse by a person not licensed or registered by the Board of Pharmacy.

(E) The following documentation must be maintained and readily retrievable:

1. The date and time prescriptions/medication orders are stocked, loaded, restocked, and removed from the Class O ADS system;

2. The date and time medications are stocked, loaded, restocked, and removed from the Class O ADS system;

3. The identity of individuals stocking, loading, restocking, or removing prescriptions/medication orders and medication in the system; and

4. For Class O ADS ambulatory prescription dispensing systems, the identity of the pharmacist responsible for verifying the contents of any manufacturer unit of use packages and repacked containers stocked, restocked, or loaded into the Class O ADS ambulatory prescription dispensing system by an intern pharmacist or pharmacy technician without a pharmacist present.

(7) Security. Adequate security and supervision must be maintained to prevent medication theft and diversion and unauthorized access to or use of the Class O ADS. Class O ADS permit holders must comply with all security provisions of this rule and 20 CSR 2220-2.010. Confidential records must be securely maintained to prevent unauthorized access to, and unauthorized storage/transfer of, confidential information.

(A) A Class O ADS must be securely placed, locked, and maintained at the address licensed by the board in a manner that prevents theft, diversion, or unauthorized access, or medication removal. Authorized access to the Class O ADS must be defined in the permit holder's policy and procedures.

(B) In addition to the requirements of section (8), written policies and procedures must be in place to immediately access, secure, remove, and store medication in the event of an emergency or security breach.

(C) The Class O ADS must have an alarm mechanism that promptly alerts a designated member(s) of the pharmacy's staff in the event of a security breach or unauthorized access to the Class O ADS. For Class O ADSs located outside of a Missouri-licensed pharmacy, the alarm must also alert local law enforcement in the event of a security breach or unauthorized access to the Class O ADS, if available. Additionally, a board licensee or registrant located in Missouri must have the authority to access and suspend operations of the Class O ADS if necessary.

(D) Confirmed or suspected security breaches of the Class O ADS must be immediately investigated. If confirmed, use/operation of the Class O ADS must immediately cease until the security breach has been rectified and proper security is restored. All security breaches of the Class O ADS must be documented and reported to the board in writing within three (3) business days of discovery.

(E) Any confirmed or suspected medication diversion/theft

must be immediately investigated. Medication diversion/theft must be reported to the board in writing within three (3) business days of discovery.

(F) A perpetual inventory must be maintained for each Class O ambulatory prescription dispensing system stocking controlled substances that is reconciled by pharmacy staff on a monthly basis.

(8) Policies and procedures. Class O permit holders must maintain current and accurate written policies and procedures governing all aspects of Class O ADS activities, including but not limited to –

(A) Staff education and training;

(B) Maintaining the Class O ADS and the accompanying electronic verification process in good working order;

(C) Maintaining and protecting system data and confidential information;

(D) Granting, restricting, or terminating Class O ADS system access;

(E) Filling, stocking, restocking, and loading the Class O ADS;

(F) Removing expired, adulterated, misbranded, or recalled medication;

(G) Temperature monitoring and documentation;

(H) Prescription processing, verification, and recordkeeping;

(I) Patient counseling;

(J) Ensuring cleanliness and sanitary operation of the Class O ADS and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(K) Emergency response procedures, including but not limited to addressing power outages and terminating and restarting Class O ADS operations;

(L) Monitoring medication inventory to prevent diversion, theft, or loss, including an escalation policy/procedure for addressing inventory discrepancies;

(M) Security requirements, including policies/procedures for authorizing Class O ADS access and terminating Class O ADS operations in the event of a confirmed or suspected security breach, inventory discrepancy, suspected loss/diversion, loss of patient confidential information, and unauthorized access to the Class O ADS;

(N) Receiving, handling, documenting, and investigating alarm notifications/alerts in the event of a security breach of the Class O ADS;

(O) Conducting routine and preventive system validation and maintenance of the Class O ADS;

(P) Quality assurance;

(Q) Handling, investigating, and reporting dispensing errors;

(R) Recordkeeping; and

(S) Data retention and retrieval.

(9) Records.

(A) Class O permit holders must maintain readily retrievable records of all Class O ADS transactions, including but not limited to all prescriptions and medication orders processed and/or dispensed by the Class O ADS and records of all medication stocked in or removed from the Class O ADS.

(B) Prescriptions and medication orders dispensed from a Class O ADS must be separately identifiable in the pharmacy's prescription records and individually retrievable from other prescriptions/medication orders maintained by the pharmacy. This requirement also applies to any Class J pharmacy dispensing prescriptions via a Class O ADS.

(C) Except as otherwise provided by this rule or other applicable law, all records required by this rule must be maintained for a minimum of two (2) years and readily retrievable on request of the board or a board-authorized designee. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from the board or the board's authorized designee, or by making a computer terminal available to the inspector for immediate use to review the records requested. Records not maintained at a pharmacy must be produced within three (3) business days of a board request.

AUTHORITY: sections 338.140, 338.210, and 338.220, RSMo Supp. 2023, and section 338.280, RSMo 2016. Original rule filed Sept. 6, 2023, effective March 30, 2024.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1951, amended 2001, 2011, 2020; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014, 2020; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.950 Automated Filling Systems

PURPOSE: This rule establishes standards for automated filling systems.

(1) Definitions. The following definitions shall be applicable for purposes of this rule:

(A) "Automated filling system" – An automated system used by a pharmacy to assist in filling a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An "automated filling system" shall not include automated devices used solely to count medication, vacuum tube drug delivery systems governed by 20 CSR 2220-2.800, or automated dispensing and storage systems governed by 20 CSR 2220-2.900 used to dispense medication directly to a patient or to an authorized health care practitioner for immediate distribution or administration to the patient;

(B) "Electronic verification system" – An electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly dispensed and labeled by, or loaded into, an automated filling system;

(C) "Manufacturer unit of use package" – A drug dispensed in the manufacturer's original and sealed packaging, or in the original and sealed packaging of a repackager, without additional manipulation or preparation by the pharmacy, except for application of the pharmacy label;

(D) "Repackager" – A repackager registered with the United States Food and Drug Administration; and

(E) "Repacked" – Any drug that has been removed from the original packaging of the manufacturer or a repackager's packaging and is placed in a container for use in an automated filling system.

(2) Medication Stocking. Automated filling systems (hereinafter "system") may be stocked or loaded by a pharmacist or by an intern pharmacist or pharmacy technician under the direct supervision of a pharmacist. Pharmacy repacked medication, cartridges, or containers shall comply with 20 CSR 2220-2.130.

(3) Verification. Except as provided herein, a licensed pharmacist shall inspect and verify the accuracy of the final contents of any medication filled or packaged by an automated filling system, and any label affixed thereto, prior to dispensing, as required by 20 CSR 2220-2.010(1)(B).

(4) The pharmacist verification requirements of section (3) shall

be deemed satisfied if –

(A) The pharmacy establishes and follows a policy and procedure manual that complies with section (5) of this rule;

(B) The filling process is fully automated from the time the filling process is initiated until a completed, labeled, and sealed prescription is produced by the automated filling system that is ready for dispensing to the patient. No manual intervention with the medication or prescription may occur after the medication is loaded into the automated filling system. For purposes of this section, manual intervention shall not include preparing a finished prescription for mailing, delivery, or storage;

(C) A pharmacist verifies the accuracy of the prescription information used by or entered into the automatic filling system for a specific patient prior to initiation of the automatic fill process. The name, initials, or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for five (5) years after dispensing;

(D) A pharmacist verifies the correct medication, repacked container, or manufacturer unit of use package was properly stocked, filled, and loaded in the automated filling system prior to initiating the fill process. Alternatively, an electronic verification system may be used for verification of manufacturer unit of use packages or repacked medication previously verified by a pharmacist;

(E) The medication to be dispensed is filled, labeled, and sealed in the prescription container by the automated filling system or dispensed by the system in a manufacturer's unit of use package or a repacked pharmacy container;

(F) An electronic verification system is used to verify the proper prescription label has been affixed to the correct medication, repackaged container, or manufacturer unit of use package for the correct patient; and

(G) Daily random quality testing is conducted by a pharmacist on a sample size of prescriptions filled by the automated filling system. The required sample size shall not be less than two percent (2%) of the prescriptions filled by the automated system on the date tested or two percent (2%) of the prescriptions filled by the automated system on the last day of system operation, as designated in writing by the pharmacist-in-charge. Proof of compliance with this subsection and random quality testing date(s) and results shall be documented and maintained in the pharmacy's records.

(5) Policies and Procedures. Pharmacies verifying prescriptions pursuant to section (4) of this rule shall establish and follow written policies and procedures to ensure the proper, safe, and secure functioning of the system. Policies and procedures shall be reviewed annually by the pharmacist-in-charge and shall be maintained in the pharmacy's records for a minimum of two (2) years. The required annual review shall be documented in the pharmacy's records and made available upon request. At a minimum, the pharmacy shall establish and follow policies and procedures for –

(A) Maintaining the automated filling system and any accompanying electronic verification system in good working order;

(B) Ensuring accurate filling, loading, and stocking of the system;

(C) Ensuring sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(D) Reporting, investigating, and addressing filling errors and system malfunctions;

(E) Testing the accuracy of the automated filling system and any accompanying electronic verification system. At a minimum, the automated filling system and electronic verification system shall be tested before the first use of the system or restarting the system and upon any modification to the automated filling system or electronic verification system that changes or alters the filling or electronic verification process;

(F) Training persons authorized to access, stock, restock, or load the automated filling system in equipment use and operations;

(G) Tracking and documenting prescription errors related to the automated filling system that are not corrected prior to dispensing to the patient. Such documentation shall be maintained for two (2) years and produced to the board upon request;

(H) Conducting routine and preventive maintenance and, if applicable, calibration;

(I) Removing expired, adulterated, misbranded, or recalled drugs;

(J) Preventing unauthorized access to the system, including, assigning, discontinuing, or changing security access;

(K) Identifying and recording persons responsible for stocking, loading, and filling the system;

(L) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements; and

(M) Maintaining an ongoing quality assurance program that monitors performance of the automatic fill system and any electronic verification system to ensure proper and accurate functioning.

(6) Recordkeeping. Except as otherwise provided herein, records required by this rule shall be maintained in the pharmacy's records electronically or in writing for a minimum of two (2) years. When the verification requirements of subsection (4)(D) of this rule are completed by a pharmacist, the name, initials, or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for five (5) years after dispensing. Records shall be made available for inspection and produced to the board or the board's authorized designee upon request.

AUTHORITY: sections 338.250 and 338.280, RSMo 2000, and sections 338.140 and 338.210.4, RSMo Supp. 2013. Original rule filed July 1, 2013, effective Jan. 30, 2014.*

**Original authority: 338.140, RSMo 1939, amended 1989, 1997, 2011; 338.210, RSMo 1951, amended 2001, 2011; 338.250, RSMo 1951, amended 1990, 1998; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-2.990 Rx Cares For Missouri Program

PURPOSE: This rule establishes the Missouri Board of Pharmacy's medication disposal program as part of the Rx Cares for Missouri Program created by section 338.710, RSMo and establishes standards/criteria for Program operation and participation.

(1) Section 338.710, RSMo, established the "Rx Cares for Missouri Program" within the Board of Pharmacy to promote medication safety and to prevent prescription drug abuse, misuse, and diversion in Missouri. As part of the Rx Cares for Missouri Program, the board is hereby establishing a medication destruction and disposal program (the "Program") for the purposes of collecting unused or unwanted medication from the public for disposal in accordance with state and federal law. Operation of the Program may be delegated to a

board approved vendor or third-party.

(2) Eligible Participants. To be eligible for participation, applicants must be physically located in Missouri and currently registered to collect unwanted controlled substances with the United States Drug Enforcement Administration ("DEA") and the Missouri Bureau of Narcotics and Dangerous Drugs ("BNDD") unless exempt from registration by state or federal law. Additionally, the applicant must be –

(A) A licensed Missouri pharmacy or drug distributor;

(B) A licensed healthcare provider authorized to prescribe controlled substances;

(C) A hospital, office, clinic, or other medical institution that provides health care services;

(D) A federal, state, local, or municipal public health, law enforcement, or other governmental agency, or

(E) A higher education institution located in Missouri that is accredited by a national or regional accrediting body recognized by the United States Secretary of Education.

(3) Participant Requirements. Approved participants must establish and operate a public medication collection program in compliance with Program requirements, including, but not limited to, all applicable board or vendor requirements for collecting, submitting, or forwarding medication for destruction and disposal. Participants must promptly enroll in the program after notification of approval is received from the board.

(A) Subject to appropriation, approved Program participants will be provided a collection receptacle and inner liners to be used for collecting medication pursuant to the Program. Participants may alternatively use an existing collection receptacle if approved by the board or the Program vendor. Program participants are responsible for installation of the collection receptacle in accordance with vendor requirements.

(B) Collection receptacles must be physically located in the state of Missouri at an address approved by the board. A board approved sign must be located on or near the receptacle indicating that the collection program has been funded by the Missouri Board of Pharmacy as part of the Rx Cares for Missouri Program. Collection receptacles may not be used to dispose of medication from the pharmacy's inventory.

(C) Medication must be collected and handled in compliance with all state and federal controlled substance laws. Program participants may submit collected medication to the vendor or the vendor's authorized designee for disposal at no cost to the participant up to twelve (12) times per participation year. Program participants may arrange for additional medication disposal at the participant's cost.

(D) Program participants shall notify the board in writing within ten (10) days after ceasing or terminating Program participation. Unless otherwise agreed by the board for good cause, Program participants shall reimburse the board for the cost of the collection receptacle if the participant fails to actively maintain and operate a collection program during the participation year. Collection receptacle costs must be remitted to the board within sixty (60) days after notification from the board.

(4) Application Procedures. Applications to participate in the Program must be submitted to the board on a board approved form and include –

(A) The applicant's name, address, contact telephone number, and e-mail address;

(B) The Missouri address where the collection receptacle will be located;

(C) A copy of the applicant's DEA and BNDD controlled substance collector registrations;

(D) A description of how the medication collection program will be operated, including operational times and how the program will be advertised to the public;

(E) A designation of whether the applicant will be using a board approved collection receptacle or supplying their own collection receptacle subject to vendor approval; and

(F) A description of the need for a medication collection program in the proposed collection site area along with any supporting data or evidence.

(5) Approval Criteria. At the discretion of the board, applicants will be approved for Program participation subject to funding availability. Participation approval shall be valid for one (1) calendar year. The following criteria will be considered by the board when reviewing applications:

(A) The need for a medication collection program in the proposed collection site area, including, but not limited to, any alternative collection programs/opportunities available;

(B) Relevant evidence or data regarding drug use, abuse, fatalities, or trends;

(C) The number of applications submitted or previously approved by the board for the applicant regardless of collection site;

(D) The nature and structure of the proposed collection program, including, but not limited to, operational times and any public restrictions;

(E) Available staff, resources, or expertise;

(F) Any state, federal, or local disciplinary action, including any pending board complaints or investigations;

(G) The applicant's compliance with state and federal drug and controlled substance laws;

(H) The applicant's financial need and available resources; and

(I) Any other factor that may be relevant to the applicant's ability to participate in or comply with the Program.

(6) Information Sharing. As a condition of participation, applicants must agree that program information collected or maintained by the vendor or the vendor's designee may be disclosed to –

(A) The board or the board's authorized designee on request; and

(B) The Missouri Governor and the Missouri General Assembly pursuant to section 338.710, RSMo.

AUTHORITY: sections 338.140 and 338.280, RSMo 2016, and sections 338.142 and 338.710, RSMo Supp. 2019. Emergency rule filed July 18, 2019, effective July 28, 2019, expired Feb. 27, 2020. Original rule filed July 18, 2019, effective Feb. 29, 2020.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.142, RSMo 2017; 338.280, RSMo 1951, amended 1971, 1981; and 338.710, RSMo 2017.*

20 CSR 2220-2.995 Board Approved Pilot and Research Projects

PURPOSE: This rule establishes application requirements and criteria for pilot projects authorized by section 338.143, RSMo.

(1) This rule establishes requirements for the approval and operation of pharmacy pilot or demonstration research

projects related to technology assisted verification or remote medication dispensing that are designed to enhance patient care or safety, improve patient outcomes, or expand access to pharmacy services, as authorized by section 338.143, RSMo.

(2) Applicants to operate a pilot program pursuant to this rule shall file an application on a form provided by the board. To be eligible, the applicant must hold a current and active license, registration, or permit from the board that is not under discipline.

(3) Proposal Requirements. Proposed pilot projects must be submitted to the board in writing and include –

(A) A one (1) page abstract of the project that includes the project's goals, purpose, scope, and proposed timelines;

(B) A narrative description of the following:

1. Activities that will be undertaken as part of the pilot project, including, the intended audience;

2. The goals and objectives of the project. Services and anticipated outcomes must be clearly described and align with section 338.143, RSMo;

3. A description of the capacity and structure the applicant has in place to operate the proposed pilot program, including, staff and personnel who will be monitoring, supervising, or participating in the pilot project and their relevant education, experience, or qualifications;

4. Procedures for training staff on project operations;

5. An explanation of how the proposal will enhance patient care or safety, improve patient outcomes, or expand access to pharmacy services for Missouri citizens;

6. A projected timeline for implementation and completion of the proposed pilot project. The proposed pilot project must be eligible for completion within eighteen (18) months of approval, unless otherwise authorized by the board;

7. Evaluation measures for assessing impact and effectiveness; and

8. A plan for pilot project termination.

(4) Pilot Projects shall be awarded at the discretion of the board with due consideration to public protection, patient safety, feasibility, the needs of the state, and the impact on pharmacy practice. Approved pilot projects shall report on program activities, as requested by the board. Approval of a pilot project may be withdrawn or rescinded by the board for the following:

(A) Any grounds authorized for discipline under section 338.055.2, RSMo;

(B) Failure to report on project operations, as requested by the board;

(C) To prevent or avoid patient harm or undue patient risk;

(D) To protect the public health, safety, or welfare; or

(E) Exceeding/Failure to comply with approved project guidelines. Deviations from approved pilot project operations must be reported to the board within five (5) business days.

AUTHORITY: sections 338.140 and 338.143, RSMo Supp. 2019. Emergency rule filed Sept. 13, 2019, effective Sept. 27, 2019, expired March 24, 2020. Original rule filed Sept. 13, 2019, effective March 30, 2020.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019 and 338.143, RSMo 2019.*

20 CSR 2220-3

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE

Division 2220—State Board of Pharmacy
Chapter 3—Negative Generic Drug Formulary

20 CSR 2220-3.010 Generic Drug Formulary

This rule originally filed as 4 CSR 220-3.010. Emergency rule filed Dec. 28, 1978, effective Jan. 7, 1979, expired April 30, 1979. Moved to 20 CSR 2220-3.010, effective Aug. 28, 2006.

20 CSR 2220-3.011 Generic Drug Substitution

PURPOSE: The purpose of this rule is to establish requirements for generic drug substitution.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Except as otherwise provided by Chapter 338, RSMo, a pharmacist who receives a prescription for a brand name drug or biological product may select a less expensive generically equivalent or interchangeable biological product unless the patient requests a brand named drug or biological product or the prescribing practitioner indicates that substitution is prohibited or displays "brand medically necessary", "dispense as written", "do not substitute", "DAW", or words of similar import on the prescription.

(2) All pharmacists and dispensing physicians should be warned that any drug product not holding an approved New Drug Application or Abbreviated New Drug Application may not be used as a substitute in the state of Missouri without the dispenser assuming some personal liability.

(3) A pharmacist shall not substitute drug products that are rated as therapeutically inequivalent to other pharmaceutically equivalent products as listed in the latest edition or cumulative supplement of *The Approved Drug Products with Therapeutic Equivalence Evaluations* published by the United States Government, Department of Health and Human Services.

AUTHORITY: section 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2019. This rule originally filed as 4 CSR 220-3.011. Emergency rule filed April 26, 1979, effective May 6, 1979, expired Aug. 12, 1979. Original rule filed April 26, 1979, effective Aug. 13, 1979. Emergency amendment filed April 14, 1982, effective April 24, 1982, expired Aug. 22, 1982. Amended: Filed April 14, 1982, effective July 11, 1982. Emergency amendment filed June 14, 1982, effective July 15, 1982, expired Oct. 12, 1982. Amended: Filed June 14, 1982, effective Sept. 11, 1982. Emergency amendment filed Dec. 6, 1982, effective Jan. 1, 1983, expired March 10, 1983. Amended: Filed Dec. 6, 1982, effective March 11, 1983. Emergency amendment filed June 14, 1983, effective July 15, 1983, expired Sept. 15, 1983. Amended: Filed June 14, 1983, effective Sept. 11, 1983. Emergency amendment filed Dec. 12, 1983, effective Jan. 1, 1984, expired March 14, 1984. Amended: Filed Dec. 12, 1983, effective May 11, 1984. Emergency amendment filed Feb. 3, 1984, effective Feb. 13, 1984, expired June 12, 1984. Emergency amendment filed June 20, 1984, effective June 30, 1984, expired Oct. 28, 1984. Amended: Filed July 9, 1984, effective Oct. 11, 1984. Emergency amendment filed Dec. 10, 1984, effective Dec. 20, 1984, expired April 19, 1985. Amended: Filed Dec. 11, 1984, effective March 11, 1985. Emergency amendment filed Jan. 18, 1985, effective Jan. 28, 1985, expired May 28, 1985. Emergency amendment filed June 14, 1985, effective June 24, 1985, expired Oct. 12, 1985. Amended: Filed June 14, 1985, effective Sept. 27, 1985. Emergency amendment filed Dec. 23, 1985, effective Jan. 2, 1986, expired June 2, 1986. Amended: Filed Dec. 23, 1985, effective May 11, 1986. Emergency amendment filed June 21, 1986, effective July 1, 1986, expired Oct. 28, 1986. Amended: Filed June 23, 1986, effective Sept. 26, 1986. Emergency amendment filed Dec. 10, 1986, effective Dec. 20, 1986, expired April 19, 1987. Amended: Filed Dec. 10, 1986, effective April 11, 1987. Emergency amendment filed July 5, 1987, effective July 20, 1987, expired Nov. 17, 1987. Amended: Filed July 7, 1987, effective Oct. 25, 1987. Emergency amendment filed Jan. 19, 1988, effective Feb. 1, 1988, expired May 30, 1988. Amended: Filed Jan. 19, 1988, effective April 28, 1988. Amended: Filed April 15, 1988, effective Jan. 1, 1989. Emergency amendment filed July 5, 1988, effective July 15, 1988, expired Nov. 12, 1988. Amended: Filed July 5, 1988, effective Nov. 11, 1988. Emergency amendment filed Jan. 19, 1989, effective Feb. 10, 1989, expired May 19, 1989. Amended: Filed Jan. 19, 1989, effective May 11, 1989. Amended: Filed March 31, 1989, effective Sept. 1, 1989. Amended: Filed Aug. 25, 1995, effective April 30, 1996. Moved to 20 CSR 2220-3.011, effective Aug. 28, 2006. Amended: Filed April 15, 2019, effective Nov. 30, 2019. ***

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019 and 338.280, RSMo 1951, amended 1971, 1981.*

***Pursuant to Executive Order 21-09, 20 CSR 2220-3.011, section (3) was suspended from April 16, 2020 through December 31, 2021.*

20 CSR 2220-3.040 Return and Reuse of Drugs and Devices

PURPOSE: This rule sets guidelines for the return and reuse of drugs and devices.

(1) Pharmacists and pharmacies shall not accept from patients or their agents for reuse or resale any drugs, prescribed medications, chemicals, poisons, or medical devices unless otherwise provided for in this regulation.

(2) A pharmacist or pharmacy may receive and reuse drugs from long-term care facilities, hospitals, and hospice facilities (as regulated by the Department of Health and Senior Services, in 19 CSR 30-35.020 Hospices Providing Direct Care in a Hospice Facility), provided that the following conditions are met:

(A) The pharmacist has assurance from a person in responsible charge of the drugs at a facility delineated in this section that the drugs being returned have been stored in accordance with the manufacturer's recommendations and meet U.S.P. standards;

(B) The drugs were originally dispensed by the pharmacist or pharmacy to the facility delineated in section (2);

(C) There is an established mechanism to trace the expiration date and the manufacturer's lot number of the drugs being returned;

(D) Only drug products dispensed by a licensed pharmacy utilizing one (1) of the following sources may be reused and no drug products for reuse shall be in any way subject to further repackaging:

1. Drug products in the original manufacturer's packaging that remains sealed in tamper-evident packaging;

2. Drug products repackaged by facilities that are federally registered as a repackager of medications and the packaging remains sealed in tamper-evident packaging;

3. Drug products that have been repackaged by a licensed pharmacy and are returned unused by the facility and remain sealed in tamper-evident packaging;

4. Drug products that have been repackaged by a licensed pharmacy and are provided in unit of use packaging whereby unused portions can be separated and reused without any further repackaging processes necessary on the returned product; and

(E) Any products that are accepted for return and can be reused based on standards provided in this rule shall be re-labeled to provide accurate information concerning patient and prescription information. Original lot numbers, expiration or beyond-use-dates assigned to a product that is reused by a pharmacy shall not be altered or in any way updated.

(3) Pharmacists and pharmacies may return to stock prescriptions that have not been received by or delivered to the patient and shall delete the dispensing from the pharmacy's records and reverse the claim with the third party payor, if applicable. In order for a product to be returned to stock, it must have been stored at all times at the manufacturer's labeled storage requirements.

(A) Except as otherwise authorized by subsection (3)(B), all drugs returned to stock that are not in the original manufacturer container must be maintained in the patient container with the dispensing date, prescription number, and name of drug visible. The expiration date of the drug shall become the lesser of one (1) year from the dispensing date on the label or the manufacturer's original expiration date, if known.

(B) Return-to-stock medication may be returned to an automated filling system unit, cell, or cartridge containing the same medication, if—

1. The prescription/medication order is returned to the automated filling system that originally dispensed it;

2. A pharmacist verifies the return-to-stock drug is properly stocked and loaded in the automated filling system;

3. The expiration date for all drugs in the unit, cell, or cartridge where medication is returned must become the shortest expiration of any drug contained in the same unit, cell, or cartridge, including, any return-to-stock medication; and

4. Drugs from different manufacturers may not be commingled in the same unit, cell, or cartridge.

AUTHORITY: section 338.280, RSMo 2016. This rule originally filed as 4 CSR 220-3.040. Original rule filed Dec. 12, 1983, effective May 11, 1984. Amended: Filed July 5, 1988, effective Nov. 11, 1988. Amended: Filed Sept. 2, 1997, effective April 30, 1998. Amended: Filed April 5, 2002, effective Nov. 30, 2002. Amended: Filed May 17, 2004, effective Dec. 30, 2004. Moved to 20 CSR 2220-3.040, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008. Amended: Filed May 13, 2020, effective Nov. 30, 2020.*

**Original authority: 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-4

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE
Division 2220—State Board of Pharmacy
Chapter 4—Fees Charged by the Board of Pharmacy

20 CSR 2220-4.010 General Fees

PURPOSE: This rule establishes and fixes the various fees and charges authorized by Chapter 338, RSMo.

(1) The following fees are established by the State Board of Pharmacy:

(A) Licensure by Examination Fee $ 150

1. Exam candidate shall contact the National Association of Boards of Pharmacy and pay any fee required directly by that agency.

(B) Licensure By Transfer of License (Reciprocity) $ 375

(C) Original Pharmacy Permit Fee $ 300

(D) Pharmacist License Renewal Fee $ 200

1. Effective from August 1, 2018 through October 31, 2018 $ 100

(E) Pharmacy Permit Renewal Fee $ 450

(F) Delinquent Pharmacist Renewal Fee (in addition to the Pharmacist License Renewal Fee) $ 250

(G) Duplicate License/Permit/ Registration Fee $ 20

(H) Change of Pharmacy, Drug Distributor, Drug Outsourcer or Third-Party Logistics Provider Name Fee $ 25

(I) Fee for Retake of Multistate Pharmacy Jurisprudence Examination (MPJE) $ 150

(J) Foreign Graduate Preliminary Filing Fee (Candidates for licensure by examination, who are graduates of schools/ colleges of pharmacy not accredited by the board) $ 250

(K) Change of Pharmacy, Drug Distributor, Drug Outsourcer, or Third-Party Logistics Provider Location Fee $ 175

(L) Original Pharmacy Distributor/ Wholesale Drug Distributor, Drug Outsourcer, or Third-Party Logistics Provider License Fee (includes both temporary and permanent license) $ 300

(M) Pharmacy Distributor/ Wholesale Drug Distributor/ Drug Outsourcer or Third-Party Logistics Provider License Renewal Fee $ 450

(N) Original Drug Distributor (Manufacturer) Registration Filing Fee $ 10

(O) Renewal of Drug Distributor (Manufacturer) Registration Filing Fee $ 10

(P) Original Intern Pharmacist License $ 50

(Q) Intern Pharmacist License Renewal $ 80

(R) Temporary Pharmacist License Fee (original issue/renewal) $ 100

(S) Fingerprint Fee for Criminal Background Check— Determined by Federal Bureau of Investigation (FBI) and Missouri State Highway Patrol (MSHP) (pass through fee)

(T) Pharmacy Technician Initial Registration Fee $ 35

(U) Pharmacy Technician Annual Renewal Fee $ 35

1. Effective from January 1, 2019 to June 1, 2019 $ 20

(V) Delinquent Continuing Education Pharmacist Fee $1000

(W) Score Transfer Fee $ 150

(X) Pharmacy Classification Change Fee $ 50

(Y) Manager-in-Charge Change Fee $ 50

(Z) Pharmacist-in-Charge Change Fee $ 50

(AA) Verification Fee $ 25

(BB) Returned Check Fee $ 25

(CC) Certification of Medication Therapeutic Plan Authority $ 50

(2) All fees are nonrefundable.

(3) The provisions of this rule are declared severable. If any fee fixed by this rule is held invalid by a court of competent jurisdiction or by the Administrative Hearing Commission, the remaining provisions of this rule shall remain in full force and effect, unless otherwise determined by a court of competent jurisdiction or by the Administrative Hearing Commission.

AUTHORITY: sections 338.020, 338.035, 338.040, 338.060, 338.070, 338.140, 338.185, 338.220, 338.230, 338.270, 338.280, 338.335, and 338.350, RSMo 2016. This rule originally filed as 4 CSR 220-4.010. Emergency rule filed July 15, 1981, effective Aug. 3, 1981, expired Nov. 11, 1981. Original rule filed Aug. 10, 1981, effective Nov. 12, 1981. Emergency amendment filed March 8, 1982, effective April 1, 1982, expired July 10, 1982. Amended: Filed March 8, 1982, effective June 11, 1982. Amended: Filed May 6, 1983, effective Aug. 15, 1983. Amended: Filed Dec. 11, 1984, effective March 11, 1985. Amended: Filed June 14, 1985, effective Aug. 26, 1985. Amended: Filed Aug. 27, 1985, effective Nov. 11, 1985. Amended: Filed Oct. 11, 1985, effective Dec. 26, 1985. Amended: Filed Dec. 16, 1985, effective May 11, 1986. Amended: Filed May 4, 1987, effective Aug. 28, 1987. Amended: Filed Jan. 19, 1988, effective April 28, 1988. Amended: Filed June 2, 1988, effective Aug. 25, 1988. Amended: Filed Dec. 10, 1990, effective June 10, 1991. Amended: Filed Feb. 4, 1991, effective June 10, 1991. Amended: Filed Aug. 4, 1992, effective April 8, 1993. Amended: Filed May 24, 1993, effective Dec. 9, 1993. Amended: Filed Oct. 17, 1994, effective May 28, 1995. Amended: Filed May 3, 1996, effective Dec. 30, 1996. Amended: Filed Jan. 6, 1997, effective July 30, 1997. Amended: Filed April 23, 1998, effective Nov. 30, 1998. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed March 1, 2001, effective Sept. 30, 2001. Amended: Filed May 17, 2004, effective Dec. 30, 2004. Amended: Filed June 15, 2005, effective Jan. 30, 2006. Moved to 20 CSR 2220-4.010, effective Aug. 28, 2006. Amended: Filed Feb. 14, 2008, effective Aug. 30, 2008. Emergency amendment filed July 6, 2012, effective July 31, 2012, expired Feb. 28, 2013. Amended: Filed July 6, 2012, effective Jan. 30, 2013. Emergency amendment filed July 8, 2014, effective July 18, 2014, expired Feb. 26, 2015. Amended: Filed July 8, 2014, effective Dec. 30, 2014. Amended: Filed Nov. 12, 2015, effective May 30, 2016. Emergency amendment filed April 11, 2017, effective April 21, 2017, expired Dec. 1, 2017. Amended: Filed April 11, 2017, effective Sept. 30, 2017. Emergency amendment filed Feb. 16, 2018, effective March 30, 2018, expired Jan. 9, 2019. Amended: Filed Feb. 16, 2018, effective Aug. 30, 2018. Emergency amendment filed Nov. 28, 2018, effective Dec. 8, 2018, expired June 5, 2019. Amended: Filed Nov. 28, 2018, effective May 30, 2019. Emergency amendment filed July 10, 2019, effective July 20, 2019, expired Nov. 5, 2019.*

**Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990, 2014; 338.035, RSMo 1990, amended 1993, 1995, 2007; 338.040, RSMo 1939, amended 1961, 1969, 1981, 1990; 338.060, RSMo 1939, amended 1943, 1947, 1949, 1951, 1981, 1984, 1997, 1999; 338.070, RSMo 1939, amended 1947, 1953, 1961, 1969, 1981, 1985, 1997; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.185, RSMo 1990; 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014; 338.230, RSMo 1951, amended 1989; 338.270, RSMo 1951, amended 1981, 2016; 338.280, RSMo 1951, amended 1971, 1981; 338.335, RSMo 1998, amended 2010; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-5

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE
Division 2220—State Board of Pharmacy
Chapter 5—Drug Distributor

20 CSR 2220-5.010 Drug Distributor Advisory Committee

PURPOSE: This rule establishes operating guidelines for the drug distributor advisory committee.

(1) As authorized in section 338.140.4., RSMo, an advisory committee, composed of five (5) members, one (1) of whom shall be a representative of pharmacy, but who shall not be a member of the pharmacy board, three (3) of whom shall be representatives of wholesale drug distributors, as defined in section 338.330, RSMo, and one (1) of whom shall be a representative of drug manufacturers, shall be appointed by the State Board of Pharmacy.

(2) Appointments to the advisory committee shall be made by the president of the board.

(A) Except for the initial committee appointments, each appointment shall be for a term of five (5) years. Beginning with the first committee appointments, the terms will be staggered so that one (1) term will expire each year after that.

(B) No appointment shall become effective until approved by the board. Each candidate shall meet with the board prior to any decision by the board to confirm. This meeting will be held in order for the board to review the candidate's credentials and to familiarize him/her with board personnel and advisory committee responsibilities.

(C) Terms of new committee members shall commence on July 1, unless the appointment is to fill an unexpired term.

(3) The advisory committee shall organize by the election of a chairman and vice-chairman who shall hold their offices for one (1) year and until their successors shall have been elected and qualified. A majority of the committee shall constitute a quorum for the transaction of business.

(4) The advisory committee shall review and make any recommendations to the board on the merit of all rules dealing with pharmacy distributors, wholesale drug distributors and drug manufacturers which are proposed by the board.

(A) The advisory committee shall maintain minutes of all meetings held.

(B) Any recommendations made by the advisory committee concerning proposed regulations shall be noted and explained in the minutes which will be provided to the board at an open session meeting of the board. The advisory committee may provide other documentation, reports or correspondence to the board when necessary.

(C) Any official recommendations to be made from the committee to the board must be initiated by a motion that receives a majority vote in favor by the committee. This motion and vote shall be recorded in the minutes.

(D) The board will review any recommendations made by the advisory committee and will provide a response to the committee if any action is taken or modifications are made to a proposed regulation. In addition, the board shall note in the *Missouri Register* the dates and a summary of any recommendations made by the advisory committee on a proposed rule and report any responses that are made to those recommendations from the board.

(5) Committee members shall be reimbursed or all reasonable and necessary expenses for attending committee meetings. However, only expenses incurred within Missouri will routinely be reimbursed. No request for the compensation of expenses provided in this rule shall be processed for payment unless sufficient funds are available for that purpose within the appropriation of the State Board of Pharmacy.

AUTHORITY: section 338.390, RSMo Supp. 1989. This rule originally filed as 4 CSR 220-5.0I0. Original rule filed Jan. 3, 1990, effective April 26, 1990. Moved to 20 CSR 2220-5.0I0, effective Aug. 28, 2006.*

**Original authority: 338.390, RSMo 1989.*

20 CSR 2220-5.020 Drug Distributor Licensing Requirements

PURPOSE: This rule defines terms and requirements for the lawful licensure of drug distributors.

(1) A "wholesale drug distributor" is defined in section 338.330(3), RSMo. No wholesale drug distributor with physical facilities located in the state of Missouri shall knowingly purchase or receive legend drugs and/or drug related devices from a wholesale drug distributor or pharmacy not licensed or registered by the board. Knowledge of the licensure status of a drug distributor or pharmacy includes, but is not limited to, actual or constructive knowledge. Knowledge of the license status of a drug distributor or pharmacy shall also include, but not be limited to, notification from the board by mail or electronic transmission.

(A) A wholesale drug distributor is further defined as anyone engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

(B) Licensure and/or registration as a wholesale drug distributer is not required for activities described below—

1. The sale, purchase, transfer, or trade of a drug or an offer to sell, purchase, transfer, or trade a drug for emergency administration to an individual patient if a delay in therapy would negatively affect a patient outcome. The amount sold, purchased, transferred, or traded shall not exceed five percent (5%) of the pharmacy's total gross prescription sales or, if prescriptions are not sold, five percent (5%) of the pharmacy's total drug purchases;

2. The sale, purchase, or trade of blood and blood components intended for transfusion and any other exemptions as provided for in Chapter 338, RSMo;

3. The sale, purchase, transfer, or trade of a drug or an offer to sell, purchase, or trade a drug by a Missouri licensed pharmacy that does not exceed five percent (5%) of the pharmacy's total gross sales. For purposes of this section, total gross sales shall be calculated based on the pharmacy's total annual prescription drug sales or, if prescriptions are not sold, five percent (5%) of the pharmacy's total drug purchases;

4. The sale, purchase, transfer, or trade of a drug or offer to sell, purchase, transfer, or trade a drug among hospitals or by a hospital to a healthcare entity under the same common control or ownership as the hospital. "Common control or ownership" means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership, stock, voting rights, contract, or otherwise. For purposes of this rule, a "hospital" shall be limited to a hospital as defined by Chapter 197, RSMo, or a hospital operated by the state;

5. The storage or distribution of drugs by a local, state, or federal facility that are received from the Strategic National Stockpile or the state stockpile for the purpose of providing those drugs in an emergency situation

as authorized by a state or federal agency;

6. The sale, purchase, or transfer of a drug or vaccine received from or on behalf of a federal, state, or municipal entity for the purpose of treating or immunizing patients during a state or federally declared disaster or emergency;

7. The sale, purchase, or transfer of a drug or vaccine subject to an emergency use authorization issued by the United States Food and Drug Administration for a public health emergency;

8. The sale, purchase, transfer, or trade of a prescription drug to alleviate a temporary shortage of a prescription drug that is in limited supply or unavailable due to delays in or interruption of supply. Drugs sold, purchased, transferred, or traded pursuant to this section shall only be sold, purchased, transferred, or traded directly from an importer or manufacturer authorized by or registered with the United States Food and Drug Administration (FDA) to import or manufacture the drug that is unavailable or in short supply. In addition, sales, purchases, transfers, or trades shall be limited to the period of shortage and to the drug that is unavailable or in limited supply. Documentation of FDA authorization or registration shall be maintained in the licensee's or recipient's records; and

9. The sale, purchase, transfer, or trade of a drug between a Missouri licensed pharmacy and a non-resident pharmacy that is located in and licensed by another state or United States territory. The total amount of drug sold, purchased, transferred, or traded by the Missouri-licensed pharmacy pursuant to this subsection shall not exceed five percent (5%) of the pharmacy's total annual prescription drug sales. Missouri pharmacies receiving drugs pursuant to this section from a non-resident pharmacy shall maintain the following records for two (2) years from the date of sale, purchase, transfer, or trade:

A. Proof the non-resident pharmacy holds a current pharmacy license in the state or territory from which the drug is shipped or distributed; and

B. An invoice record which documents the name and address of the non-resident pharmacy, the date of sale, purchase, transfer, or trade, and the name, strength, and quantity of the drug received. The pharmacies shall also comply with all applicable controlled substance requirements.

(C) Wholesale drug distributors shall inform the board of their current FAX number, any change in FAX number, and/or the fact that the wholesale drug distributor does not have a working FAX. In the event a wholesale drug distributor notifies the board that the wholesale drug distributor does not have a working FAX, notification from the board will be made to the wholesale drug distributor by first class mail. For the purposes of this rule, such notification by mail shall be considered effective three (3) days after mailing and shall have the same effect as notification by FAX.

(D) Failure to receive notification from the board shall not be a defense to violations of section (1) of this rule when the wholesale drug distributor has failed to comply with the requirements of subsection (1)(C) of this rule.

(2) All licenses for the operation of a drug distributor shall expire on the date specified by the director of the Division of Professional Registration by appropriate rule.

(3) Drug distributor licenses shall be issued on the application of the owners. If the owner is a corporation, an officer of the corporation must sign the application as the applicant. If the owner is a partnership, a partner must sign the application as the applicant. If the owner is a limited liability partnership, a general partner must sign the application as the applicant. If the owner is a limited liability company, a member must sign the application as the applicant.

(4) Drug distributor license applications and renewal applications shall be completed and submitted to the Board of Pharmacy along with the appropriate fees before any license is issued or renewed. Information required on the application shall include:

(A) The name, full business address, electronic facsimile transmission number (FAX), and telephone number of the licensee;

(B) All trade or business names used by the licensee;

(C) The address, telephone number, and the name of the manager in charge for each facility used by the licensee for the storage, handling, and distribution of prescription drugs;

(D) The type of ownership or operation;

(E) The name(s) of the owner, operator, or both, of the licensed entity, including:

1. If a person, the name of the person;

2. If a partnership, the name of each partner and the name of the partnership;

3. If a corporation, the name of the corporate president, vice president, secretary, treasurer, chief executive officer, board of directors, and senior vice presidents or their equivalents, the corporate name(s), and the name of the state of incorporation; and

4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(F) The name of the manager-in-charge who meets the requirements as set forth in 20 CSR 2220-5.030(2); a complete notarized manager-in-charge affidavit of the license application; and a history of employment/occupations and offices held during the past seven (7) years; and

(G) An application for a wholesale or pharmacy drug distributor license will become null and void if the applicant fails to complete the process for licensure within six (6) months of receipt of the application by the board.

(5) When a drug distributor changes ownership, the original license becomes void on the effective date of the change of ownership. Before any new business entity resulting from that change opens a facility as a drug distributor, it must obtain a new license from the board. A temporary license shall be issued once a completed application and fee have been received by the board. The effective date of the temporary license shall be the date the change of ownership is listed as effective on the application. Such license shall remain in effect until a permanent license is issued or denied by the board.

(A) A change of ownership of a drug distributor facility owned by a sole proprietor is deemed to have occurred when—

1. The business is sold and the sale becomes final;

2. The proprietor enters into a partnership with another individual or business entity; or

3. The proprietor dies; provided, however, that the proprietor's estate may continue to operate the drug distributor facility for a period of no more than one (1) year and only so long as appropriate fees are paid.

(B) If a corporation owns a drug distributor facility, it is not necessary to obtain a new license if the owners of the stock change. If a limited liability partnership or a limited liability company owns a drug distributor company, it is not necessary to obtain a new license if the partners or members of the company change, as long as the partnership or company is not dissolved by that change. It is necessary to file written notice with the Board of Pharmacy within thirty (30) days after a change occurs of twenty-five percent (25%) or more in the ownership of corporation stock, or in partners in a limited liability partnership, or in members of the limited liability company. This notification must be in writing and certified. However, when a corporation, limited liability partnership, or limited liability company begins ownership of a drug distributor company or ceases ownership of a drug distributor company, a new license must be obtained regardless of the relationship between the previous and subsequent owners.

(6) If an individual or business entity operating a drug distributor facility changes the location of the facility either within the existing facility (structure) or to a new facility (structure), the facility shall not open for business at the new location until the board, its duly authorized agent, or the Food and Drug Administration has inspected the premises of the new location and approved it and the facility has been in compliance with all state and federal drug laws pertaining to drug distribution. Upon this approval and receipt of a change of location fee, the board shall issue a license authorizing operation of a facility at the new location and the license shall bear the same number as the previous license. However, the license remains valid if the facility address changes, but not the location, and an amended license will be issued without charge under these circumstances.

(7) Separate licenses shall be required for each drug distribution site owned or operated by a drug distributor as defined in section 338.330, RSMo.

(8) The Board of Pharmacy may grant a temporary license to a wholesale or pharmacy drug distributor to allow for the conduct of business within the state until a determination by the board is made on the issuance of a permanent license.

(A) Temporary licenses shall remain valid until a time the board shall find that the applicant meets or fails to meet the requirements for regular licensure or one (1) year, whichever is less.

1. The board will consider, at a minimum, the following factors in reviewing the qualifications of persons who apply or renew as a drug distributor:

A. Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

B. The person has been finally adjudicated and found guilty, or entered a plea of guilty or *nolo contendere*, in a criminal prosecution under the laws of any state or of the United States, for any offense reasonably related to the qualifications, functions, or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud, dishonesty, or an act of violence, or for any offense involving moral turpitude, whether or not sentence is imposed;

C. The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

D. The applicant furnishing false or fraudulent material in any application made in connection with drug manufacturing or distribution;

E. Suspension, revocation, or probation by federal, state, or local government of any license or registration currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

F. Compliance with licensing requirements under previously granted licenses, if any; and

G. Requirements to maintain or make available, or both, to the board or the federal, state, or local law enforcement officials those records required under this section are followed.

2. If an applicant for a license in any way fails to provide information as requested by the board or does not cooperate with requests and inquiries made by the board or provides false or misleading information to the board and the temporary license expires or is denied, all fees paid by the applicant shall be forfeited.

3. During the period of time that a temporary license is in effect, the applicant may conduct business in this state as a drug distributor as long as all state and federal laws governing drug distribution are followed and no action that results in professional misconduct as outlined in section 338.055, RSMo is documented.

4. If it is determined by the board that a permanent license is to be denied to an applicant, a denial notification letter shall be sent to the applicant. The temporary license will be considered invalid ten (10) days after notification is sent to the applicant by certified mail.

(B) A license must be posted in a conspicuous place in the facility to which it is issued.

(9) Each licensed corporate wholesale distributor located outside of this state that distributes drugs in this state shall designate a registered agent in this state for service of process. Any licensed corporate wholesale distributor that does not designate a registered agent shall be deemed to have designated the secretary of state of this state to be its true and lawful attorney, upon who may be served all legal process in any action or proceeding against any licensed corporate wholesale distributor growing out of or arising from such distribution. Service of process shall be accomplished as authorized by law.

AUTHORITY: sections 338.335 and 338.350, RSMo 2016, and sections 338.140.1, 338.315, 338.330, 338.333, 338.337, and 338.340, RSMo Supp. 2020. This rule originally filed as 4 CSR 220-5.020. Original rule filed Feb. 4, 1991, effective June 10, 1991. Amended: Filed April 28, 1992, effective Feb. 26, 1993. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed April 6, 2001, effective Nov. 30, 2001. Amended: Filed June 16, 2003, effective Jan. 30, 2004. Amended: Filed June 15, 2005, effective Jan. 30, 2006. Moved to 20 CSR 2220-5.020, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007. Amended: Filed Oct. 27, 2014, effective May 30, 2015. Emergency amendment filed Oct. 29, 2020, effective Nov. 13, 2020, expired May 11, 2021. Amended: Filed Oct. 29, 2020, effective April 30, 2021.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.315, RSMo 1989, amended 2011, 2012, 2014, 2018; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; 338.333, RSMo 1989, amended 2010, 2012, 2018; 338.335, RSMo 1998, amended 2010; 338.337, RSMo 1989, amended 2009, 2010, 2018; 338.340, RSMo 1989, amended 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-5.025 Termination of Business as a Drug Distributor

PURPOSE: This establishes guidelines for the termination of business as a drug distributor.

(1) A licensed drug distributor who plans to terminate business activities shall file a written notice with the State Board of Pharmacy. The written notice shall be submitted to the State Board of Pharmacy in person or by registered or certified mail within (15) days after the date of termination. This notice shall be made on a form provided by the board or in letter form from the license and shall include the following information:

(A) The name, address, license number and effective date of closure;

(B) The name, address and license number of the entity to which any of the stock/inventory will be transferred; and

(C) The name and address of the location to which records, required to be maintained by law, have been transferred;

1. Any records that are transferred to an unlicensed location must be retrievable for board review within seven (7) working days of a request made by an authorized official of the board;

2. Any records that are transferred to a licensed drug distributor or pharmacy must be maintained in accordance with record requirements as set forth in 4 CSR 220-5.030.

(2) The licensee terminating business may transfer all drugs and records in accordance with the following:

(A) On the date of termination, a complete inventory of all controlled substances being transferred or disposed of shall be completed according to state and federal laws. This inventory shall serve as the final inventory of the drug distributor terminatoring business and as the initial inventory of the licensed entity to which the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee involved in the transfer;

(B) A drug distributor terminating business shall not transfer misbranded, outdated or adultered drugs, except for purposes of proper disposal; and

(C) Upon the actual termination of business, the license of the drug distributor shall be returned to the State Board of Pharmacy for cancellation either in person or by registered or certified mail.

(3) The requirements of this rule are not intended to replace or be in conflict with any other laws or regulations governing the appropriate licensure, change of ownership or change of location of a drug distributor.

(4) The termination date is the date on which the drug distributor licensee ceases to do business as a distributor as defined in section 338.330(1), (2) or (3), RSMo in the state of Missouri.

AUTHORITY: sections 338.333 and 338.350, RSMo 1994. This rule originally filed as 4 CSR 220-5.025. Original rule filed May 4, 1995, effective Dec. 30, 1995. Moved to 20 CSR 2220-5.025, effective Aug. 28, 2006.*

**Original authority: 338,333, RSMo 1989 and 338.350, RSMo 1989, amended 1993.*

20 CSR 2220-5.030 Definitions and Standards for Drug Wholesale and Pharmacy Distributors

PURPOSE: This rule provides standards for the proper storage, maintenance, labeling and distribution of drugs by drug wholesale and pharmacy distributors, and further defines methods of inspections and quality assurance used by the Board of Pharmacy to ensure the public's safety in these areas. For purposes of this rule, the term drug distributor will be used to define all entities that are licensed under section 338.330, RSMo and are subject to this rule.

(1) Drug distributors must maintain standards of practice that will ensure that only drugs of appropriate quality will be distributed to practitioners for further compounding and dispensing to the public. These standards shall be subject to periodic reviews through the board's inspection process.

(A) This process will include on-site inspections for drug distributors who are located in this state and may include border states or by requesting information on licensure and inspections conducted by other states or the federal government through the board office.

(B) For purposes of this rule, the term drug distributor, when used, defines anyone engaged in any activity as defined in section 338.330, RSMo.

(2) No drug distributor license will be issued unless the facility is under the direct supervision of a manager-in-charge.

(A) The board shall consider the same factors in reviewing the qualifications of someone who is appointed as a manager-in-charge as those outlined in 20 CSR 2220-5.020(8)(A)1.

(B) A person must also have appropriate education, experience, or both, before assuming the duties of manager-in-charge. Appropriate education for purposes of this section is defined as education in the areas of work environment, standards of operation and knowledge of laws concerning drug distributor compliance and requirements.

1. Minimum requirements for education/experience may be attained separately or in combination to total two (2) years.

2. Experience within a drug wholesale or pharmacy distributor facility or in any education endeavor beyond a certificate of graduation from an accredited high school or its equivalent may be utilized in meeting these minimum requirements.

(C) Any individual that is considered a manager or supervisor within a facility but is not the manager-in-charge of the facility must meet the minimum education/experience requirements as set forth in this rule for a total of one (1) year.

(D) The licensee shall require all other persons employed in any prescription drug wholesale distribution activity to have education, training and experience, or any combination, sufficient for that person to perform the assigned functions in a manner as to provide assurance that the drug product quality, safety and security at all times will be maintained as required by law.

(E) Drug distributor operations must be conducted at all times under the supervision of a properly designated manager-in-charge. The manager-in-charge must be actively involved and aware of the actual daily operations of the drug distributor operation. The manager-in-charge must be physically present at the drug distributor operation during normal business hours, except for time periods when absent due to illness, scheduled vacation or other authorized absence; and be aware of, and knowledgeable about, all polices and procedures pertaining to the operations of the drug distributor operation. When the person who is manager-in-charge resigns or is terminated from the position, the holder of the license shall immediately notify the board office of the resignation or termination of the manager-in-charge and by notarized affidavit give the name of the new manager-in-charge.

(3) Minimum standards of practice for drug distributors shall include the following:

(A) The facility must be of a suitable size and construction to facilitate cleaning, maintenance and proper operations;

(B) The temperature of the facility where drugs are stored must be maintained thermostatically within temperature requirements as provided for by the manufacturer or the latest edition of the *United States Pharmacopeia* (USP). Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, logs, or all of these, shall be utilized to document proper storage of prescription drugs;

(C) Appropriate housekeeping, sanitation, lighting, ventilation and humidity of all areas where drugs are stored must be maintained.

1. All aisles and walkways must be free and clear of debris, dirt or filth.

2. Dust shall be kept at low levels through adequate ventilation, cleaning procedures, or both.

3. All shelves and storage areas shall be kept free of debris, dirt, dust and filth.

4. Full cases of drug products shall be raised above floor level and placed on a pallet or similar device.

5. Upon receipt of legend drugs, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

6. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

7. Drugs stored in a facility or being processed for distribution must be physically separated at all times from articles, supplies or other drugs that are outdated, distressed,

misbranded or adulterated. An area separate from drug storage must be used to store quarantined, nonusable substances or accumulated waste/garbage. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier. If a drug is received or further distributed, either directly or through a secondary broker (paper) transaction, that is wholly or in part found to be counterfeit, a report which includes the name of the drug, quantity and lot number(s) must be forwarded to the Board of Pharmacy within seven (7) days of gaining knowledge of the transaction. Any recall of a product that is initiated by the Food and Drug Administration (FDA) or by a vendor licensed with the state of Missouri shall not be subject to the reporting requirement.

8. Flammable articles must be stored separately and away from drug products held for later wholesale distribution.

9. Drugs which may be held for later distribution that are labeled for veterinary use must be stored separately from those drugs that are to be distributed for human use.

10. Procedures must be in place to prevent, control and alleviate infestation by insects, rodents, birds or vermin of any kind. Animals, except for service animals as defined by the Americans with Disabilities Act (ADA), are not allowed in the drug storage areas.

11. Appropriate sewage disposal and a hot and cold water supply must be available.

12. The outside perimeter of the premises shall be well-lighted.

13. All facilities shall be equipped with an alarm system to detect entry after hours.

14. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records;

(D) The drug distributor license issued to the facility must be displayed in a public area;

(E) Adequate refrigeration must be available to ensure enough storage space for drugs requiring refrigeration or freezing and under temperatures adequate to maintain the drug products as recommended by the manufacturer, the latest edition of the USP, or both;

(F) The labeling of drug products held for wholesale distribution must conform to requirements as set forth by the manufacturer, FDA, the USP and section 338.059.2, RSMo;

(G) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug distributor shall consider, among other things, the conditions under which the drug has been held, stored or shipped before or during its return and the condition of the drug and its container, carton or labeling, as a result of storage or shipping;

(H) Drugs held for wholesale distribution must be stored in a secure area where only authorized personnel have access to them. Sufficient locking mechanisms must be in place and a list of personnel who possess keys or passes which allow them to have independent access to any part of a facility which stores drugs held for later distribution or where any controlled substances are stored must be maintained. Records on all past employees who have had access to drug storage or processing areas must be maintained for a period of three (3) years;

(I) Wholesale drug and pharmacy distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

1. The source of the drugs, including the name and principal address of the seller or transferor and the address of the location from which the drugs were shipped;

2. The identity and quantity of the drugs received and distributed or disposed of; and

3. The dates of receipt and distribution or other disposition of the drugs;

(J) Inventories and records shall be made available for inspection and photocopying by authorized federal, state or local law enforcement agency officials for a period of three (3) years following disposition of the drugs;

(K) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by the board or its representatives;

(L) Record requirements as described in this rule shall be followed for appropriate accountability and disposition for all outdated, damaged, deteriorated, misbranded or adulterated prescription drugs;

(M) Wholesale drug and pharmacy distributors shall establish, maintain and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Drug distributors shall include in their written policies and procedures the following:

1. A procedure where the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate;

2. A procedure to be followed for handling recalls and withdrawals of prescription drugs. This procedure shall be adequate to deal with recalls and withdrawals due to any—

A. Action initiated at the request of the FDA or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;

B. Voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

C. Action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

3. A procedure to ensure that drug distributors prepare for, protect against and handle any crisis that affects the security or operation of any facility in the event of strike, fire, flood or other natural disaster, or other situations of local, state or national emergency;

4. A procedure for reporting counterfeit or suspected counterfeit drugs or devices or counterfeiting or suspected counterfeiting activities to the board;

5. A procedure for the mandatory reporting to the board and any other appropriate federal or state agency of all shortages of prescription drugs and devices where it is known or suspected that diversion or theft is occurring;

6. A procedure for investigating discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband in the inventory and reporting such discrepancies within seven (7) business days to the board and any other appropriate federal or state agency shall be maintained by each drug distributor;

7. A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) and device(s) to the board within the seven (7) business days; and

8. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for three (3) years after disposition of the outdated drugs.

(N) Drug distributors will be responsible for security procedures for the delivery of drugs from the wholesale facility to the destination site of all drug shipments; and

(O) No drug distributor license shall be issued to any location, regardless of zoning, that is a residence or that shares an address and/or physical space with a business not related to the distribution of prescription drugs or drug-related devices, or not licensed and regulated by the state of Missouri.

(4) In addition to standards listed in this rule for drug distributors, drug repackagers must observe federal standards for—

(A) Packaging;
(B) Record keeping;
(C) Expiration dating;
(D) Plant facilities;
(E) Equipment;
(F) Personnel;
(G) Production and control procedures;
(H) Containers;
(I) Testing; and
(J) Federal registration requirements.

(5) Agents or employees of licensed or registered drug distributors may have legend drugs in their custody if they are acting in the usual course of business or employment and their names and addresses and the addresses of all sites where drugs are stored have been provided to the board.

(A) Storage and transport of drugs by agents or employees of drug distributors must be maintained in accordance with manufacturer or USP guidelines and must be free of contamination, deterioration or adulteration.

(B) Drug distributors shall report to the board any agents or employees that are registered pursuant to this section of this rule for any convictions for violations of state or federal drug laws.

(6) Drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(7) Drug distributors shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including Parts 207, 210 and 211 of the Federal Food, Drug and Cosmetic Act.

(8) The executive director of the board, at his/her discretion, may grant exemptions to compliance with portions of section (3) of this rule when such exemptions are not contrary to federal drug distributor laws and the exemption is limited to a specific request. Any exemption requests by a licensed drug distributor must be submitted in writing. Any exemptions that are granted as outlined in this section will be provided in writing.

(9) As used in section 338.330(3), RSMo, the term "drug related device" shall be defined as an article that is not considered a prescription drug under federal law, but which meets the definition of a device as provided in 21 U.S.C. 321(h) and 21 U.S.C. 360j(e).

AUTHORITY: sections 338.333, 338.343 and 338.350, RSMo 2000. This rule originally filed as 4 CSR 220-5.030. Original rule filed Feb. 4, 1991, effective June 10, 1991. Amended: Filed Jan. 27, 1995, effective Sept. 30, 1995. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Amended: Filed Nov. 1, 2000, effective June 30, 2001. Amended: Filed May 13, 2005, effective Oct. 30, 2005. Moved to 20 CSR 2220-5.030, effective Aug. 28, 2006. Amended: Filed Aug. 21, 2006, effective April 30, 2007. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008.*

**Original authority: 338.333, RSMo 1989; 338.343, RSMo 1989, amended 1993; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-5.040 Drug Distributor Inspection Exemptions

PURPOSE: This rule defines requirements for Board of Pharmacy inspection exemption of wholesale drug and pharmacy distributors.

(1) Inspections of drug distribution facilities shall be conducted by the board in accordance with the provisions as outlined in section 338.360, RSMo. Any drug distributor facility which has been inspected by the Food and Drug Administration (FDA) over a period of less than two (2) years and can demonstrate that all inspections resulted in a satisfactory rating shall be exempt from further inspection by the board until and upon the time that any inspection of the premises of the facility results in a less than satisfactory rating or the last full inspection by the FDA is two (2) years old or greater.

(A) For purposes of this rule, the results of federal inspections that are deemed to be less than satisfactory shall include, but not be limited to, any documentation as to deficiencies in any drug distribution, repackaging, labeling, quality control or environmental policies or procedures, or both. Deficiencies may be defined as any statement which is a part of a compliance report recorded by federal inspection with or without sanctions, penalties, fines or discipline imposed.

1. For purposes of further definition, an inspection that is conducted by the FDA that is used for exemption purposes must be a full inspection of all operations and procedures of the facility. Abbreviated inspectional options as defined in federal policy guidelines may not be considered to fulfill the exemption requirements as provided in section 338.360, RSMo and this rule.

2. Any drug distribution facility which has been granted an exemption from inspection must notify the board at any time of an inspection conducted by the FDA or the Drug Enforcement Administration that results in less than a satisfactory rating as defined in subsection (1)(A) of this rule.

AUTHORITY: section 338.350, RSMo Supp. 1989. This rule originally filed as 4 CSR 220-5.040. Original rule filed Feb. 4, 1991, effective June 10, 1991. Moved to 20 CSR 2220-5.040, effective Aug. 28, 2006.*

**Original authority: 338.350, RSMo 1989.*

20 CSR 2220-5.050 Out-of-State Distributor License/Registration Requirements

PURPOSE: This rule establishes guidelines for license/registration procedures for out-of-state drug distributors.

(1) Out-of-state wholesale drug distributors or out-of-state pharmacy distributors may be licensed, as required by sections 338.210—338.370, RSMo, by reciprocity if they—

(A) Possess a valid license in good standing in the state or foreign jurisdiction in which they are located pursuant to legal standards comparable to those which must be met by a distributor of this state as prerequisites for obtaining a license under the laws of this state; and

(B) Are located in a state or foreign jurisdiction which extends reciprocal treatment under its own laws to a wholesale distributor of this state.

(2) Out-of-state wholesale drug and pharmacy distributors shall not ship, mail or deliver prescription drugs into Missouri without first

obtaining a license from the Missouri Board of Pharmacy.

(A) In order for an out-of-state wholesale drug or pharmacy distributor to maintain a license, it must comply with each of the following:

1. Maintain in good standing a license from the state or foreign jurisdiction in which the nonresident distributor is located provided that a license is issued by that state or foreign jurisdiction;

2. Submit an application as provided by the board for licensure in compliance with sections 338.333 and 338.337, RSMo and with 4 CSR 220-5.020;

3. Pay all appropriate fees;

4. Submit a copy of the state or foreign jurisdiction license or its equivalent from the state or foreign jurisdiction in which the distributor is located provided that a license is issued by that state or foreign jurisdiction;

5. Submit a copy of the state or foreign jurisdiction and federal controlled substance registrations from the state or foreign jurisdiction in which they are located, if controlled substances are to be shipped into Missouri; and

6. Submit copies, when requested by the board, of any inspection reports, warning notices, notice of deficiency reports or any other related reports from the state or foreign jurisdiction in which it is located concerning the operation of an out-of-state drug or pharmacy distributor for review of compliance with state, federal or foreign jurisdiction drug laws.

(B) The Missouri Board of Pharmacy will extend reciprocal cooperation to any state or foreign jurisdiction that licenses and regulates out-of-state drug or pharmacy distributors for the purpose of investigating complaints against distributors located in Missouri or the sharing of information and investigative reports, as long as the other state or foreign jurisdiction will extend the same reciprocal cooperation to the Missouri Board of Pharmacy.

(3) An exemption to licensure is allowed when an out-of-state wholesale drug distributor supplies a drug to another drug distributor licensed in this state in an emergency situation. The amount of the distribution allowed must be confined to the emergency situation and the total amount of distribution for emergency situations must not exceed one percent (1%) of the total annual gross sales of the unlicensed distribution site.

(4) Registration in lieu of licensure may be sought by an out-of-state drug distributor when the following provisions exist:

(A) The out-of-state drug distributor is a drug manufacturer;

(B) The manufacturing facility is used for both the production (manufacture) and distribution of legend drugs;

(C) The site has been inspected with a satisfactory rating by the Food and Drug Administration within the last two (2) years. Inspections of these facilities must comply with all standards and requirements as outlined in 4 CSR 220-5.040;

(D) The state in which the manufacturing facility is located issues a license and the license is current and in good standing; and

(E) The out-of-state distributor who qualifies for registration must complete an application as provided by the board and submit it along with a filing fee of ten dollars ($10).

1. The board shall provide, on an annual basis, a registration renewal form to all registered out-of-state distributors.

2. In order for a registration to remain in good standing and in effect, the renewal must be returned to the Division of Professional Registration by an expiration date that is specified by the director of the division by appropriate rule.

3. In order for a registration to be renewed, it must comply with all the provisions for registering as a drug distributor facility as outlined in section 338.337, RSMo and this rule.

4. Each renewal application must be submitted along with a filing fee of ten dollars ($10).

AUTHORITY: sections 338.330, 338.335 and 338.350, RSMo Supp. 1999 and 338.333 and 338.337, RSMo 1994. This rule originally filed as 4 CSR 220-5.050. Original rule filed Feb. 4, 1991, effective June 10, 1991. Amended: Filed March 15, 2000, effective Sept. 30, 2000. Moved to 20 CSR 2220-5.050, effective Aug. 28, 2006.*

**Original authority: 338.330, RSMo 1989, amended 1993, 1998; 338.333, RSMo 1989; 338.335, RSMo 1998; 338.337, RSMo 1989; 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-5.060 Controlled Substance Reporting

PURPOSE: This rule defines requirements for reporting the distribution of controlled substances from drug and pharmacy distributors to persons and facilities that are registered with the Federal Drug Enforcement Administration.

(1) Wholesale drug and pharmacy distributors that distribute Schedule II products and Schedule III narcotics Automation of Reports and Consolidated Orders (ARCOS products) shall provide a listing of those products distributed within the state to the board on a quarterly basis when requested to do so by the board. In addition, wholesale drug and pharmacy distributors that distribute controlled substances within the state shall provide up to a twenty-four (24) month retrospective listing of all controlled substances (Schedule II through Schedule IV) distributed within the state or to a specific location to the board when requested to do so by the board. The board shall submit the request thirty (30) days in advance of the information requested. Reports must be submitted to the board either on hard copy in typewritten form or by electronic media. If electronic media is used in providing the reports, it shall be provided in one (1) of the following formats.

(A) If an electronic tape is used, it shall be an IBM 9-track, labeled or nonlabeled, 1600 or 6250 bits per inch (bpi);

(B) If a diskette is used, it shall be either a MacIntosh 400K or 800K; MS-DOS 5 1/4" 360K or 1.2 meg; MS-DOS 3 1/2" 720K or 1.44 meg; or an IBM 8" diskette; or

(C) If a cartridge is used, it shall be a 1/2" tape, 3480 Compatible.

AUTHORITY: section 338.350, RSMo Supp. 1989. This rule originally filed as 4 CSR 220-5.060. Original rule filed Jan. 3, 1992, effective Aug. 6, 1992. Moved to 20 CSR 2220-5.060, effective Aug. 28, 2006.*

**Original authority: 338.350, RSMo 1989.*

20 CSR 2220-5.070 Standards of Operation for Medical Gas Distributors

PURPOSE: This rule establishes standards of operation for medical gas distributors. This proposed rule has been reviewed by the Drug Distributor Advisory Committee as required by section 338.140.4, RSMo.

(1) Medical gases are defined as compressed gases and liquid gases that a distributor or manufacturer has labeled for medical use in compliance with federal law.

(2) Medical gas distributor is defined as an entity which is licensed by the board as a drug distributor and is involved in the distribution of medical gases and related medical devices pursuant to a medical gas order to medical gas suppliers and other entities that are registered, licensed or permitted to use, administer or distribute medical gases.

(3) Medical gas distributors that are not involved in the storage or transfer of any

other federal legend drugs and only store, transfer or transfill medical grade gas products other than nitrous oxide are exempt from the following regulation sections: 20 CSR 2220-5.030(3)(B); (3)(C)4., 9., 12., and 13.; (3)(E); and (3)(M)4. Medical gas distributors that store, transfer or transfill nitrous oxide are exempt from 20 CSR 2220-5.030(3)(B); (3)(C)4. and 9.; (3)(E) and (3)(M)4. All other drug distributor requirements contained within the board's regulations shall be considered applicable to medical gas distributors.

(4) A medical gas distributor that is involved in the manufacture/transfilling of medical gases must register with the Food and Drug Administration (FDA) as a medical gas manufacturer and comply with the drug listing requirements of the federal act. In addition, all current good manufacturing practice requirements as set forth in 21 CFR 210 through 211 must be complied with.

AUTHORITY: sections 338.050, 338.333, 338.335, 338.337, and 338.340, RSMo 2000. This rule originally filed as 4 CSR 220-5.070. Original rule filed March 15, 2000, effective Sept. 30, 2000. Moved to 20 CSR 2220-5.070, effective Aug. 28, 2006. Amended: Filed Feb. 6, 2008, effective Aug. 30, 2008.*

**Original authority: 338.050, RSMo 1939, amended 1949, 1961, 1971, 1981; 338.333, RSMo 1989; 338.335, RSMo 1998; 338.337, RSMo 1989; and 338.340, RSMo 1989.*

20 CSR 2220-6

TITLE 20 – DEPARTMENT OF COMMERCE AND INSURANCE
Division 2220 – State Board of Pharmacy
Chapter 6 – Pharmaceutical Care Standards

20 CSR 2220-6.025 HIV Post-Exposure Prophylaxis

PURPOSE: This rule establishes requirements for authorized pharmacists dispensing HIV post-exposure prophylaxis as authorized by section 338.730, RSMo.

(1) Definitions.

(A) Authorized pharmacist – A Missouri-licensed pharmacist who has completed a training course or certificate program in HIV antiretroviral prophylaxis that includes training in CDC guidelines for HIV PEP.

(B) Authorizing physician – A physician identified in a written protocol as authorizing a pharmacist to dispense HIV PEP and who will be collaborating with an authorized pharmacist in HIV PEP dispensing.

(C) CDC guidelines – The current human immunodeficiency virus (HIV) guidelines published by the federal Centers for Disease Control and Prevention (CDC) for non-occupational and occupational HIV exposure.

(D) Medical staff committee – The medical staff committee of a hospital or hospital system as defined by section 338.165, RSMo, that includes a Missouri-licensed physician, or the medical staff committee or similar body of a Missouri-licensed long-term care facility that includes a Missouri-licensed physician and is responsible for formulating policies regarding pharmacy services and medication management for the long-term care facility.

(E) Pharmacy resident – A graduate of a pharmacy school/college accredited by the Accreditation Council for Pharmacy Education (ACPE) who is a licensed pharmacist enrolled in a residency training program accredited by the American Society of Health-System Pharmacists, a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists, or a residency program operated by or in conjunction with an ACPE-accredited school or college of pharmacy.

(F) Physician – An individual who is actively engaged in the practice of medicine in the state of Missouri and holds a current Missouri physician and surgeon license pursuant to Chapter 334, RSMo, which is not encumbered in any way, such as by designation as probated, restricted, limited, temporary, inactive, or retired;

(G) Post-exposure prophylaxis (PEP) – Any medication approved by the Food and Drug Administration (FDA) that meets the same clinical eligibility recommendations provided in CDC guidelines.

(H) Protocol – For purposes of section 338.730, RSMo, and this rule, a protocol is defined as –

1. A written protocol approved by a Missouri-licensed physician that meets the minimum standards in section (2) of this rule and agreed to by the authorized pharmacist who would be dispensing HIV PEP;

2. A written protocol approved by the medical staff committee of a hospital or hospital system as defined by section 338.165, RSMo, that includes a Missouri-licensed physician;

3. A written protocol approved by the medical staff committee of a Missouri-licensed long-term care facility that includes a Missouri-licensed physician; or

4. A standing order issued by the Director of the Missouri Department of Health and Senior Services (DHSS) if a physician, or by a physician approved and designated by DHSS.

(2) Authorized pharmacists may enter a written protocol to prescribe and dispense HIV PEP, as provided by section 338.730, RSMo. HIV PEP protocols must be within the skill, education, training, and competence of both the authorizing physician and authorized pharmacist.

(A) HIV PEP protocols must adhere to CDC guidelines and include specific directions for the authorized pharmacist to follow. Except as otherwise provided by DHSS for a DHSS protocol, HIV PEP protocols must, at a minimum, include the following:

1. Directions/guidelines for patient assessment and counseling;

2. Authorized drug therapies to be dispensed including the specified dosage regimen and dosage forms;

3. Authorized route(s) of administration;

4. Specific requirements for referring patients to a healthcare provider for additional evaluation/treatment;

5. Any patient counseling requirements designated by the authorizing physician; and

6. Any documentation or recordkeeping required by the authorizing physician.

(B) Protocols may include provisions that allow an authorized pharmacist to create a prescription in the physician's name for HIV PEP medication. The prescription must comply with all applicable state and federal law. The prescription may be dispensed by a licensed pharmacy and must be maintained in the prescription records of the dispensing pharmacy as provided by the Missouri State Board of Pharmacy's rules.

(C) Protocols may allow the authorized pharmacist to order or perform testing as authorized by the protocol physician or medical staff committee. If the protocol includes conducting physical assessments or ordering and evaluating laboratory or other tests, the protocol must identify required assessments, authorized tests to be ordered, the criteria for ordering the assessments and tests, interpretation of assessments/tests, and what action the authorized pharmacist is authorized to take based on assessment/test results.

(D) Except as otherwise authorized for a DHSS statewide standing order, protocols must be signed and dated by the authorizing physician and the authorized pharmacist. If the protocol includes multiple physicians or authorized pharmacists, a separate protocol is not required for each physician or authorized pharmacist if all authorizing physicians and authorized pharmacists have signed and dated a statement agreeing to be governed by the terms of the written protocol. Unless otherwise required by DHSS, a HIV PEP statewide standing order is exempt from the signature/dating requirements of this subsection. When utilizing the HIV PEP statewide standing order issued by DHSS, the pharmacist or the designee of the pharmacist shall periodically review the HIV PEP statewide standing order and ensure it is current and active.

(E) Pharmacy residents. In lieu of an individual protocol, a pharmacy resident may dispense HIV PEP as part of their residency training under the HIV PEP protocol of an authorized pharmacist, if authorized by the governing protocol.

(F) Protocols must be physically or electronically maintained by both the authorizing physician and authorized pharmacist and available to the Board of Pharmacy and the Board of Registration for the Healing Arts for a minimum of eight (8) years after termination of the protocol.

(G) DHSS protocols shall be governed by and comply with all DHSS requirements and provisions.

(3) Compliance and Supervision.

(A) Authorized pharmacists must ensure patient care activities are safely and properly performed in accordance with the governing protocol, recognized standards of practice, and current CDC guidelines. Additionally, authorized pharmacists must comply with all applicable provisions of Chapter 338, RSMo, and the rules of the Board of Pharmacy governing prescribing and recordkeeping.

(B) The authorizing physician shall be responsible for overseeing compliance with protocol requirements, section 338.730, RSMo, and current CDC guidelines, but may designate such responsibilities to a pharmacist if a medication therapy services protocol is in place that includes dispensing HIV PEP. Except as otherwise provided by a DHSS protocol, the authorizing physician or a designee of the authorizing physician who is a Missouri-licensed healthcare provider must be available to –

1. Provide follow-up appointments for care of patients who received PEP pursuant to a HIV PEP protocol, or maintain a list of physician, surgeons, clinics, or other Missouri-licensed healthcare providers who the authorizing physician or the designee of the authorizing physician confirmed are willing and able to accept referrals of patients within a reasonable time of the authorized pharmacist initiating HIV PEP and deliver care; and

2. Respond to calls/inquiries from the authorized pharmacist regarding HIV PEP dispensing, treatment, or patient assessment.

(4) Authorized pharmacists prescribing/dispensing HIV PEP pursuant to a DHSS standing order must comply with all DHSS requirements. Authorized pharmacists must comply with the following requirements when prescribing/dispensing HIV PEP based on all other protocols:

(A) Unless otherwise provided by CDC guidelines or restricted by the governing protocol, an authorized pharmacist may dispense a twenty-eight- (28-) day course of HIV PEP therapy, if all of the following conditions are met:

1. The patient is thirteen (13) years of age or older;

2. The patient is HIV negative, as documented by a negative HIV test result obtained within the previous twenty-four (24) hours from an HIV antigen/antibody test or antibody-only test or from a rapid, point-of-care fingerstick blood test approved by the federal Food and Drug Administration. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the authorized pharmacist shall order an HIV test. If the test results are not transmitted directly to the authorized pharmacist, the pharmacist shall verify the test results to the authorized pharmacist's satisfaction. If the patient tests positive for HIV infection, the authorized pharmacist must immediately notify the patient and refer the patient to the patient's primary care provider if known, and provide a list of providers and clinics in the patient's region for confirmatory testing and follow-up care. If an HIV test is not reasonably available for twenty-four (24) hours or longer, the authorized pharmacist may use clinical discretion to dispense HIV PEP upon verification that other criteria for dispensing has been met and HIV PEP is otherwise indicated;

3. The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms;

4. The patient is not taking any contraindicated medications per guidelines and package insert information;

5. The single high-risk event of non-occupational exposure to HIV occurred within seventy-two (72) hours of the pharmacist-patient encounter; and

6. An authorized pharmacist may not dispense HIV PEP to an individual patient by protocol more than twice every three hundred sixty-five (365) days. The authorized pharmacist must notify the patient of the three hundred sixty-five- (365-) day limit and advise the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for PEP if the patient exceeds the three hundred sixty-five- (365-) day dispensing limit;

(B) Authorized pharmacists must counsel patients on the safe and appropriate use of HIV PEP to maximize therapeutic outcomes. Counseling may include, but is not limited to, education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of childbearing capacity. The authorized pharmacist should stress the importance of ongoing monitoring and follow-up care with a primary care provider, and recommend routine primary care and health maintenance. Authorized pharmacists must also notify patients that confirmation HIV testing is recommended at three (3) and six (6) months or the interval(s) recommended by the CDC;

(C) Because of the importance of follow-up care and the potential difficulty of obtaining an appointment on short notice, authorized pharmacists must provide patients prescribed or dispensed HIV PEP a list of, and addresses and contact information for, nearby federally qualified health centers, local county health departments, hospitals, emergency departments, or other governmental providers/agencies that may provide follow-up care or HIV testing, treatment, or counseling for the patient; and

(D) The authorized pharmacist must notify the patient's primary care provider when the pharmacist prescribes/dispenses HIV PEP to the patient. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the authorized pharmacist must provide the patient a list of physicians and surgeons, clinics, or other healthcare service providers who the authorizing physician or the designee of the authorizing physician confirmed are willing and able to accept new or uninsured patients and deliver care in a timely fashion. The required list must be developed in consultation with or approved by the authorizing physician, and must be updated by December 31 of each calendar year and as needed to ensure patients have access to follow-up care and success with obtaining appointments. If the patient does not have a primary care provider, the authorized pharmacist must also recommend that the patient use a patient healthcare navigator or community healthcare case worker as defined by the CDC to access healthcare services. An authorized pharmacist must document authorization from the patient prior to facilitating referrals, coordinating follow-up care, or making appointments with a provider on the patient's behalf.

(5) Mandatory Referrals/Reporting. Authorized pharmacists must make the following referrals when prescribing/dispensing HIV PEP by protocol:

(A) An authorized pharmacist shall not prescribe or dispense HIV PEP and must immediately refer the patient to an emergency department or a primary care provider for urgent treatment if the patient is under thirteen (13) years old or is taking any contraindicated medications per guidelines and package insert information;

(B) If a patient tests positive for HIV infection, a sexually

transmitted disease, or hepatitis B or C, the authorized pharmacist must refer or direct the patient to a primary care provider and provide the patient a list of providers or clinics in the patient's region for confirmatory testing and follow-up care;

(C) If the patient returns to the authorized pharmacist for follow-up care and shows signs or symptoms of acute renal injury, acute HIV infection, acute drug toxicities, or serious side effects after taking HIV PEP, the authorized pharmacist shall immediately refer the patient to an emergency department for urgent evaluation and treatment; and

(D) Authorized pharmacists shall report actual or suspected child abuse or neglect to the Missouri Department of Social Services, Children's Division, as required by Missouri law, including but not limited to sections 210.115 and 210.130, RSMo. If the case involves a known sexual assault victim, the authorized pharmacist shall refer the patient to an emergency department, and recommend that the patient contact law enforcement and be examined and co-managed by professionals trained in assessing and counseling individuals who have been sexually assaulted.

(6) Patient Medical Records. Authorized pharmacists shall maintain a patient medical record for each patient that documents the care provided for the patient pursuant to a HIV PEP protocol.

(A) At a minimum, the required patient medical record must include:

1. The patient's name, birthdate, address, and telephone number;
2. The date(s) the patient was seen;
3. The name or identity of the authorized pharmacist;
4. The patient's primary care provider, if provided;
5. Documentation of patient screening;
6. All information required by the governing protocol or requested by the authorizing physician;
7. Any other pertinent medical or medication information/history;
8. The name and dosage of medication dispensed or prescribed under the authorizing physician's name; and
9. Any healthcare provider referrals.

(B) Patient medical records must be individually retrievable and must be securely and confidentially maintained in compliance with applicable state and federal law. At a minimum, patient medical records must be maintained for seven (7) years from the date created. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from a board or a board's authorized designee. Records not maintained at a pharmacy must be produced within three (3) business days of a board request.

(C) Patient records for pharmacy services provided by an authorized pharmacist pursuant to an HIV PEP protocol must be produced to the authorizing physician or medical staff committee on request.

(7) Production of Records. Records maintained at a pharmacy must be produced during an inspection or investigation by the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, or their authorized representatives, as requested by the respective board or the board's designee. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

AUTHORITY: sections 338.140, 338.210, and 338.730, RSMo Supp. 2022. Original rule filed Aug. 10, 2022, effective Feb. 28, 2023.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; 338.210, RSMo 1957, amended 2001, 2011, 2020; and 338.730, RSMo 2021.*

20 CSR 2220-6.030 Provision of Drug and/or Medical Information

(Rescinded November 30, 2019)

AUTHORITY: sections 338.095, RSMo Supp. 1993, 338.010, RSMo Supp. 1990, 338.140, RSMo Supp. 1989 and 338.280, RSMo 1986. This rule originally filed as 4 CSR 220-6.030. Original rule filed March 1, 1994, effective Sept. 30, 1994. Moved to 20 CSR 2220-6.030, effective Aug. 28, 2006. Rescinded: Filed May 13, 2019, effective Nov. 30, 2019.

20 CSR 2220-6.040 Administration by Medical Prescription Order

PURPOSE: This rule establishes procedures for pharmacists to administer medication pursuant to a medical prescription order.

(1) A pharmacist who complies with the provisions of this rule may administer drugs and devices pursuant to a medical prescription order, including vaccines.

(2) Except as otherwise provided by law, a pharmacist may not delegate medication administration to another person, except to an intern pharmacist or qualified pharmacy technician who has met the qualifications under subsections (3)(B)–(E) and is working under the direct supervision of a pharmacist who has met the qualifications to administer drugs pursuant to a medical order.

(A) For purposes of this rule, a "qualified pharmacy technician" is defined as a currently registered Missouri pharmacy technician who –

1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies;
2. Has an initial and, if applicable, annual documented assessment of competency in medication administration; and
3. Has assisted in the practice of pharmacy as a registered/licensed pharmacy technician in the state of Missouri or another U.S. state or territory for a minimum of one (1) year.

(B) Proof of an intern's or qualified pharmacy technician's compliance with subsections (3)(B)–(E) must be maintained by both the supervising pharmacist and the intern pharmacist/qualified pharmacy technician for a minimum of two (2) years.

(3) Pharmacist Qualifications. A pharmacist who is administering drugs pursuant to a medical prescription order must first file a Notification of Intent to administer drugs by medical prescription order with the board. To file a Notification of Intent, a pharmacist must –

(A) Hold a current Missouri pharmacist license;

(B) Hold a current healthcare provider level cardiopulmonary resuscitation (CPR) certification or Basic Life Support certification issued by the American Heart Association, the American Red Cross, or an equivalent organization. The certificate program must have included an in-person skills assessment;

(C) Have successfully completed a certificate program in medication administration and emergency procedures accredited by the Accreditation Council for Pharmacy Education (ACPE), provided by an ACPE or regionally accredited pharmacy or medical school/college or approved by the Board of Pharmacy. The required training program must provide instruction in –

1. Administration techniques, including hands-on training in routes of administration;
2. Drug storage and handling;
3. Informed consent requirements;
4. Pre- and post- administration assessment and counseling;
5. Biohazard waste disposal; and
6. Identifying and treating adverse reactions, including anaphylactic reactions and needle sticks;

(D) If a pharmacist wishes to administer drugs by a route of administration not included in the original certification program, the pharmacist must first be trained in the techniques of that route of administration by a licensed health care practitioner who is authorized to administer medication. Documentation of the required training and training date(s) must be maintained at the pharmacy and available to the board on request; and

(E) Proof of compliance with this section must be maintained for a minimum of two (2) years.

(4) General Requirements.

(A) Medication must be administered in compliance with all applicable state and federal laws, including applicable Vaccine Information Statements and informed consent requirements. Except as otherwise authorized by law, vaccines must also be administered in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC) or in accordance with manufacturer's guidelines.

(B) Pharmacists must have a current and accurate written policy and procedure manual covering all aspects of administering drugs by medical prescription order, including:

1. Drug administration procedures;
2. Authorized routes of administration;
3. Drug storage;
4. Pre- and post- administration assessment and counseling;
5. Biohazard waste disposal and disposal of used/contaminated supplies;
6. Identifying and handling acute adverse events or immunization reactions, including anaphylactic reactions; and
7. Recordkeeping and notification procedures and requirements.

(C) Drugs must be stored within the manufacturer's labeled requirements, including when administering outside of a pharmacy. Vaccines must be stored in accordance with CDC guidelines at all times.

(D) Patients must be asked to remain in the pharmacy a safe amount of time after administering a vaccine to observe any adverse reactions, as required by section 338.010, RSMo.

(5) Requirements of Medical Prescription Order for Administration. At a minimum, the medical prescription order from a licensed prescriber must include:

(A) The name of the licensed prescriber issuing or authorizing the order;

(B) The name of the patient to receive the drug;

(C) The name of the drug and dose to be administered;

(D) The route of administration;

(E) The date of the original order; and

(F) The date or schedule, if any, of each subsequent administration.

(6) Record Keeping.

(A) Pharmacists administering or supervising administration of medication pursuant to this rule shall ensure the following records are manually or electronically maintained separate from the prescription files of a pharmacy for each administration:

1. The name, address, and date of birth of the patient;
2. The date, route, and anatomic site of the administration;
3. The medication name and dose. For vaccines and biologics, the manufacturer, expiration date, and lot number must also be documented and recorded;
4. For vaccines, the name and address of the patient's primary health care provider, as identified by the patient or an indication that a primary health care provider was not provided;
5. The identity of the administering pharmacist, or if applicable, the administering intern pharmacist or qualified pharmacy technician and his/her supervising pharmacist; and
6. If applicable, the nature of an adverse reaction and who was notified.

(B) All records required by this regulation must be kept by the pharmacist for two (2) years from the date of such record. Except as otherwise required by section (3), records must be kept at the pharmacy where the prescription order is maintained. If not administered on behalf of a pharmacy, records not maintained at a pharmacy may be securely stored at a location designated by the pharmacist. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from the board or the board's authorized designee. Records not maintained at a pharmacy must be produced within three (3) business days of a board request.

(7) Notification Requirements. Pharmacists administering or supervising administration of medication under this rule, shall ensure –

(A) For vaccines, a pharmacist shall inform the patient that the administration of the vaccine will be entered into the ShowMeVax system, as administered by the Department of Health and Senior Services. The patient shall attest to the inclusion of such information in the system by signing a form provided by the pharmacist. Entry into ShowMeVax must occur within fourteen (14) days. If the patient indicates that he or she does not want such information entered into the ShowMeVax system, the pharmacist must provide a written report within fourteen (14) days of administration of a vaccine to the patient's primary health care provider, if provided by the patient, containing –

1. The identity of the patient;
2. The identity of the vaccine or vaccines administered;
3. The route of administration;
4. The anatomic site of the administration;
5. The dose administered; and
6. The date of administration;

(B) The prescriber is notified within twenty-four (24) hours after learning of an adverse event or reaction experienced by a patient following administration. Notification is mandatory and cannot be waived. Vaccine adverse events or reactions must also be reported to the Vaccine Adverse Event Reporting System (VAERS) or its successor, within thirty (30) days;

(C) Any notifications required by state and federal law are properly completed and documented; and

(D) Notifications required by this section may be made electronically or in writing or via a common electronic medication record that is accessible to and shared by both the physician

and pharmacist. Documentation of the required notifications, including the notification date, must be maintained as required by subsection (6)(B) or electronically retrievable at the request of the board or the board's authorized designee.

(8) Notification of Intent Refiling. To continue administration, a Notification of Intent to administer drugs by medical prescription order must be refiled with the board biennially along with the pharmacist's Missouri pharmacist license. To refile, a pharmacist must meet the requirements of subsection (3)(B) above.

(9) A qualified pharmacy technician administering medication pursuant to this rule must be supervised by a Missouri-licensed pharmacist who is authorized to administer medication pursuant to this rule and who is physically present on-site when the medication is administered.

AUTHORITY: section 338.280, RSMo 2016, and sections 338.010.1 and 338.140, RSMo Supp. 2020. Emergency rule filed May 1, 2008, effective May 11, 2008, expired Feb. 18, 2009. Original rule filed May 1, 2008, effective Nov. 30, 2008. Amended: Filed Dec. 15, 2017, effective June 30, 2018. ** Emergency amendment filed Nov. 25, 2020, effective Dec. 11, 2020, expired June 8, 2021. Amended: Filed Nov. 25, 2020, effective May 30, 2021.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

***Pursuant to Executive Order 21-07, 20 CSR 2220-6.040, section (8) was suspended from July 13, 2020 through August 5, 2021.*

20 CSR 2220-6.050 Administration of Vaccines

PURPOSE: This rule establishes procedures for pharmacists administering vaccines as authorized by section 338.010.1, RSMo.

(1) A Missouri licensed pharmacist may order and administer vaccines as authorized by section 338.010.1, RSMo. Pharmacists must be competent to perform the services provided and maintain ongoing/continued competency. Except as otherwise authorized by law, for purposes of section 338.010.1(4), RSMo, pharmacists may administer reformulated or updated versions of vaccines authorized by the U.S. Food and Drug Administration (FDA) after January 1, 2023, provided the initial vaccine was approved by the FDA prior to January 1, 2023.

(A) Vaccines must be administered in accordance with current treatment guidelines established by the Centers for Disease Control (CDC) and the manufacturer's guidelines, provided CDC guidelines shall control in the event of a conflict. Vaccines may not be administered to persons under seven (7) years of age unless otherwise authorized by law.

(B) Pharmacists shall ensure compliance with all state and federal laws and regulations pertaining to Vaccine Information Statements and informed consent requirements.

(C) Vaccines must be stored in accordance with CDC guidelines/recommendations and within the manufacturer's labeled requirements, including, when vaccinating outside of a pharmacy.

(D) A pharmacist may only delegate vaccine administration to an intern pharmacist or qualified pharmacy technician who has met the qualifications of subsections (3)(B) and (C) of this rule and is working under the direct supervision of a pharmacist qualified to administer vaccines. Proof of an intern's or qualified pharmacy technician's compliance with subsections (3)(B) and (C) must be maintained by both the supervising pharmacist and the intern pharmacist/qualifying pharmacy technician for a minimum of two (2) years.

(E) For purposes of this rule, a "qualified pharmacy technician" is defined as a currently registered Missouri pharmacy technician who –

1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies;

2. Has an initial and, if applicable, annual documented assessment of competency in vaccine administration; and

3. Has assisted in the practice of pharmacy as a registered/licensed pharmacy technician in the state of Missouri or another U.S. state or territory for a minimum of one (1) year.

(2) For vaccines administered by protocol, the authorizing protocol physician is responsible for the oversight of, and accepts responsibility for, the vaccines administered by the pharmacist.

(3) Pharmacist Qualifications. Pharmacists administering vaccines as authorized by section 338.010.1, RSMo, must first file a Notification of Intent (NOI) to administer vaccines with the Missouri Board of Pharmacy via the Board of Pharmacy's website or on a form provided by the Board of Pharmacy. To file a NOI, a pharmacist must –

(A) Hold a current Missouri pharmacist license;

(B) Hold a current healthcare provider level cardiopulmonary resuscitation (CPR) or basic life support (BLS) certification issued by the American Heart Association, the American Red Cross, or an equivalent organization. The qualifying BLS or CPR certification program must have included a live in-person skills assessment; and

(C) Have successfully completed a certificate program in administering vaccines accredited by the Accreditation Council for Pharmacy Education (ACPE), provided by an ACPE or regionally accredited pharmacy or medical school/college or approved by the Board of Pharmacy. The required certificate program must include a live/in-person training component and include instruction in –

1. Current CDC guidelines and recommendations for vaccines authorized by Chapter 338, RSMo, including recommended immunization schedules;

2. Basic immunology and vaccine protection;

3. Physiology and techniques for vaccine administration, including hands-on training in intramuscular, intradermal, subcutaneous and nasal administration routes, and other common routes of vaccine administration;

4. Pre- and post- vaccine screening or assessment; and

5. Identifying and treating adverse immunization reactions;

(D) Prior to administering vaccines by a route of administration not included in the original certificate program, the pharmacist must first be trained in the techniques of that route of administration by a licensed health care practitioner who is authorized to administer medication. Documentation of the required training and training date(s) must be maintained and available to the board on request.

(4) Pharmacist immunization activities must be safely and properly performed in accordance with the applicable standard of care.

(A) An adequate patient or medical history must be collected as deemed necessary or appropriate to allow the pharmacist to properly assess the patient.

(B) Prior to ordering or administering a vaccine authorized

by Chapter 338, RSMo, the pharmacist shall use a screening procedure based on generally accepted clinical guidelines to identify appropriate patients for immunization. The pharmacist shall refer patients with a contraindication to the patient's primary care provider or an appropriate health care provider, as deemed necessary or appropriate.

(C) Pharmacists ordering or administering a vaccine as authorized by section 338.010, RSMo, may create a prescription in the pharmacist's name or, if applicable, the name of the authorizing protocol physician. The prescription may be dispensed by a licensed pharmacy and must be maintained in the prescription records of the dispensing pharmacy as provided by the Board of Pharmacy's rules. In addition to this rule, pharmacists shall comply with all applicable provisions of Chapter 338, RSMo, and the rules of the Board of Pharmacy governing prescribing and record-keeping, including but not limited to 20 CSR 2220-2.018.

(5) Protocol Requirements.

(A) A Missouri licensed pharmacist may enter into a written protocol with a Missouri licensed physician to order and administer vaccines authorized by section 338.010.1(4), RSMo. The written protocol may be valid for a time period not to exceed one (1) year. The protocol must be renewed annually and include the following:

1. The identity of the participating pharmacist and authorizing protocol physician;
2. Time period of the protocol;
3. Authorized vaccines;
4. The patient or groups of patients authorized for vaccination;
5. Allowed routes and anatomic sites of administration;
6. If applicable, authorization to create a prescription for each administration under the authorizing protocol physician's name;
7. Patient assessment or referral requirements, if applicable;
8. Emergency response procedures, including but not limited to procedures for handling/addressing adverse reactions, anaphylactic reactions, and accidental needle sticks;
9. The length of time the pharmacist must observe an individual for adverse events following an injection;
10. Procedures for disposing of used and contaminated supplies;
11. Authorization to administer vaccines at a non-pharmacy location, if applicable;
12. Record-keeping requirements and any required notification procedures; and
13. A provision allowing termination of the protocol at any time at the request of any party.

(B) The protocol, and any subsequent amendments or alterations, must be reviewed and manually or electronically signed and dated by the pharmacist and authorizing protocol physician prior to its implementation, signifying that both are aware of its contents and agree to follow the terms of the protocol. A copy of the protocol must be maintained by both the pharmacist and the authorizing protocol physician for a minimum of eight (8) years after termination of the protocol.

(C) Additional pharmacists or immunization locations may be added to an existing protocol if the amendment is signed and dated by the authorizing protocol physician(s) and, if applicable, any newly added pharmacist(s). Existing pharmacists are not required to re-sign the protocol unless other protocol terms or provisions are changed.

(6) Record Keeping.

(A) Within seventy-two (72) hours after a vaccine is administered, a prescription must be created in the ordering pharmacist's name for any vaccine dispensed. For vaccines provided pursuant to an immunization protocol with a Missouri licensed physician, the prescription must be obtained from the authorizing protocol physician for any vaccine dispensed or a prescription must be created in the authorizing protocol physician's name, documenting the dispensing within seventy-two (72) hours as authorized by protocol.

(B) For vaccines ordered by a pharmacist, the pharmacist must maintain a patient record of each vaccine ordered that includes –

1. The patient's name, address, and date of birth;
2. The date, route, and anatomic site of the administration;
3. The vaccine's name, dose, manufacturer, lot number, and expiration date;
4. The name and address of the patient's primary health care provider, as provided by the patient;
5. The identity of the administering pharmacist or, if applicable, the identity of the administering intern pharmacist or qualified pharmacy technician and supervising pharmacist;
6. Documentation of patient screening, if applicable;
7. The nature of any adverse reaction and who was notified, if applicable; and
8. Any other pertinent medical or medication information/history.

(C) The pharmacist shall ensure a record is maintained for each vaccine administered pursuant to section 338.010.1(4), RSMo, that includes –

1. The patient's name, address, and date of birth;
2. The date, route, and anatomic site of the administration;
3. The vaccine's name, dose, manufacturer, lot number, and expiration date;
4. The name and address of the patient's primary health care provider, as provided by the patient;
5. The identity of the administering pharmacist or, if applicable, the identity of the administering intern pharmacist or qualified pharmacy technician and supervising pharmacist;
6. Documentation of patient screening, if applicable;
7. The nature of any adverse reaction and who was notified, if applicable; and
8. Any other pertinent medical or medication information/history.

(D) Notwithstanding any other provision of this rule, prescription records must be maintained as provided by Chapter 338, RSMo, and the rules of the board.

(E) The records required by this rule must be securely and confidentially maintained as follows:

1. If the vaccine is administered on behalf of a pharmacy, both the pharmacy and the pharmacist shall ensure the records required by subsections (6)(A)–(C) are promptly delivered to and maintained at the pharmacy separate from the pharmacy's prescription files;
2. If the vaccine is not being administered on behalf of a pharmacy, all records shall be maintained securely and confidentially by the pharmacist at an address identified in advance by the pharmacist or, if applicable, identified in the protocol;
3. Prescription records must be maintained as required by Chapter 338, RSMo, and the rules of the board; and
4. Records required by this rule must be maintained for two (2) years and made available for inspecting and copying by the State Board of Pharmacy or the State Board of Registration for the Healing Arts and/or their authorized representatives.

Records maintained at a pharmacy must be produced during an inspection by the board and/or their authorized representatives. Records not maintained at a pharmacy must be produced within three (3) business days after a request from the State Board of Pharmacy, the Board of Registration for the Healing Arts, and/or their authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

(7) Notification of Immunizations. Pharmacists immunizing pursuant to section 338.010.1(4), RSMo, must –

(A) Notify all persons or entities as required by state and federal law;

(B) Notify the authorizing protocol physician as required by the governing protocol, if applicable;

(C) Notify the patient's primary care provider as required by Chapter 338, RSMo; and

(D) Notify the patient's primary health care provider and, if different, the authorizing protocol physician, within twenty-four (24) hours after learning of any adverse event or reaction experienced by the patient. Adverse events or reactions must also be reported to the Vaccine Adverse Event Reporting System (VAERS) or its successor, within thirty (30) days.

(E) Unless otherwise provided by a governing protocol, notification may be made via a common electronic medication record that is accessible to and shared by both the authorizing protocol physician and pharmacist. Proof of notification must be maintained in the pharmacist's records as provided in subsection (6)(B) of this rule.

(8) Notification of Intent Renewal. A Notification of Intent (NOI) to immunize as authorized by section 338.010.1(4), RSMo, must be renewed biennially with the immunizing pharmacist's Missouri pharmacist license. To renew a NOI, pharmacists must –

(A) Have a current healthcare provider cardiopulmonary resuscitation (CPR) or basic life support (BLS) certification that complies with subsection (3)(B) of this rule; and

(B) Have completed a minimum of two (2) hours of continuing education (0.2 CEU) related to administering vaccines or CDC immunization guidelines in a course approved by the Board of Pharmacy or provided by an ACPE accredited continuing education provider within the applicable pharmacist biennial renewal period (November 1 to October 31 of the immediately preceding even numbered years).

(C) The required continuing education (CE) shall be governed by 20 CSR 2220-7.080 and may be used to satisfy the pharmacist's biennial continuing education requirements. The initial training program required by section (3) of this rule may be used to satisfy the CE requirements of this subsection if the training program was completed within the applicable pharmacist biennial renewal cycle.

(9) A qualified pharmacy technician immunizing pursuant to this rule must be supervised by a Missouri-licensed pharmacist who is authorized to immunize pursuant to section 338.010, RSMo, and who is physically present on-site when the vaccine is administered.

AUTHORITY: sections 338.010, 338.140, and 338.220, RSMo Supp. 2023. Emergency rule filed Oct. 24, 2007, effective Nov. 3, 2007, expired April 30, 2008. Original rule filed Oct. 24, 2007, effective May 30, 2008. Emergency amendment filed Oct. 22, 2009, effective Nov. 1, 2009, expired April 29, 2010. Amended: Filed Oct. 22, 2009, effective June 30, 2010. Amended: Filed Feb. 9, 2018, effective Sept. 30, 2018. ** Emergency amendment filed Jan. 4, 2021, effective Jan. 19, 2021, expired July 17, 2021. Amended: Filed Jan. 4, 2021, effective July 30, 2021. Emergency amendment filed Aug. 14, 2023, effective Aug. 28, 2023, expired Feb. 23, 2024. Amended: Filed Aug. 14, 2023, effective Jan. 30, 2024.*

Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019, 2021, 2023; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014, 2020.

***Pursuant to Executive Order 21-09, 20 CSR 2220-6.050, subsections (7)(A) and (7)(B) was suspended from July 13, 2020 through December 31, 2021.*

20 CSR 2220-6.055 Non-Dispensing Activities

PURPOSE: This rule establishes procedures and requirements for the performance of non-dispensing activities outside of a pharmacy.

(1) Pursuant to section 338.220, RSMo, a pharmacist may perform the following non-dispensing activities outside of a licensed pharmacy:

(A) Patient counseling/education, as authorized by Missouri law, provided the pharmacist shall be obligated to comply with 20 CSR 2220-2.190, when applicable;

(B) Obtain patient history/information;

(C) Review patient records/medical histories;

(D) Patient assessment/evaluation, as authorized by Missouri law;

(E) Billing and insurance claim submissions/review;

(F) Drug utilization review;

(G) Assess health plan and medication eligibility/coverage;

(H) Pharmacy compliance audits/evaluations;

(I) Administer drugs, vaccines, or biologicals, as authorized by law and the rules of the board;

(J) Peer review/peer consultations;

(K) Review, select, and develop formularies or plan/practice guidelines;

(L) Review compliance with benefit guidelines;

(M) Manage inventory, including purchasing and ordering;

(N) Manage/review information systems;

(O) Patient medication review;

(P) Consultation with other health care professionals;

(Q) Patient referrals;

(R) Prescription order entry/review, provided that a pharmacist shall only be authorized to accept a prescription on the premises of a Missouri licensed pharmacy, as required by section 338.095.5, RSMo; and

(S) Medication therapy management, pursuant to and as authorized by Chapter 338, RSMo, and the rules of the board.

(2) Confidentiality. A pharmacist, pharmacy technician, or intern pharmacist performing non-dispensing activities pursuant to this rule shall comply with all applicable state and federal confidentiality laws and regulations. Sufficient storage and security for confidential documents and electronic data processing hardware must be provided by the pharmacy permit holder or the pharmacist. In addition, data processing systems must utilize sufficient security software to ensure confidentiality and prevent unauthorized access. Any breach in the security or confidentiality of the data processing systems or confidential documents shall be documented and reported to the board in writing within seven (7) days of the breach.

(3) Notwithstanding any other provision of this rule, a pharmacist shall not meet with patients in the pharmacist's residence or living quarters.

(4) A pharmacist, pharmacy technician, or intern pharmacist performing non-dispensing activities pursuant to this rule shall ensure compliance with Chapter 338, RSMo, and the rules of the board at all times. Nothing in this rule shall be construed to eliminate or otherwise exempt any pharmacist, pharmacy technician, intern pharmacist, or pharmacy permit holder from the record-keeping, confidentiality, or security requirements otherwise imposed by Chapter 338, RSMo, or the rules of the board. Violations of this section shall constitute grounds for discipline.

(5) This rule shall not be construed to authorize a pharmacist to conduct the unauthorized practice of medicine or to conduct any activity for which a license is required pursuant to Chapters 330, 331, 332, 334, or 337, RSMo.

(6) A pharmacy technician and intern pharmacist may be used to assist a pharmacist with non-dispensing activities outside of a pharmacy subject to the following:

(A) The pharmacy technician/intern pharmacist must be under the direct supervision of a Missouri licensed pharmacist as required by 20 CSR 2220-2.710. The supervising pharmacist must ensure pharmacy technician/intern pharmacist activities comply with state and federal law and must provide the personal assistance, direction, and approval required to verify and ensure delegated non-dispensing activities are safely and properly performed;

(B) The pharmacy technician or intern pharmacist must have completed employer approved training in the activities performed and have an initial and, if applicable, annual documented assessment of proficiency. Documentation of the completed training and proficiency assessment must be maintained in the pharmacy's records for a minimum of two (2) years and provided to the board or the board's designee upon request;

(C) A sufficient mechanism must be in place to allow real-time communication between a pharmacist and the technician/intern pharmacist when needed. A pharmacist must be available to respond to pharmacy technician/intern pharmacist questions at all times non-dispensing activities are being performed; and

(D) Adequate security and supervision must be maintained at all times to prevent unauthorized access to, and unauthorized storage/transfer of, confidential patient information or patient records.

(E) The provisions of this section (6) do not apply to technicians or intern pharmacists engaged in delivering filled prescriptions/medication orders on behalf of the pharmacy as authorized by 20 CSR 2220-2.013.

AUTHORITY: sections 338.010 and 338.140, RSMo Supp. 2019, and sections 338.035 and 338.220, RSMo 2016. Emergency rule filed Oct. 23, 2009, effective Nov. 2, 2009, expired April 30, 2010. Original rule filed Oct. 22, 2009, effective June 30, 2010. ** Amended: Filed Feb. 7, 2020, effective Aug. 30, 2020. Emergency amendment filed June 5, 2020, effective June 19, 2020, expired Sept. 1, 2020.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019; 338.035, RSMo 1990, amended 1993, 1995, 2007; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.220, RSMo 1951, amended 1969, 1981, 1989, 1997, 1999, 2001, 2004, 2007, 2009, 2011, 2013, 2014.*

***Pursuant to Executive Order 21-09, 20 CSR 2220-6.055, section (6) was suspended from March 20, 2020 through December 31, 2021.*

20 CSR 2220-6.060 General Provisions

PURPOSE: This rule establishes definitions for 20 CSR 2220-6.060 to 20 CSR 2220-6.080 governing medication therapy services by pharmacists.

(1) Definitions. The following definitions shall apply for purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080:

(A) Authorizing physician(s) – The physician identified in the written protocol as authorizing the pharmacist to provide medication therapy services;

(B) Health care entity – For purposes of this rule, a health care entity shall be defined as any entity or organization that is licensed or certified by the state or federal government as a hospital, hospice facility, ambulatory surgical center, nursing home, long-term care facility, residential care facility, assisted living facility, intermediate care facility, skilled nursing facility, or a habilitation center as defined by Chapter 630, RSMo, and that is required to maintain patient medical records by state or federal law;

(C) Medication therapy protocol – A written agreement between a physician and a pharmacist for the provision of medication therapy services. A medication therapy protocol shall comply with the provisions of 20 CSR 2220-6.080;

(D) Medication therapy services – The designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has authority to initiate or implement a modification of the patient's medication therapy or device usage pursuant to a medication therapy protocol. For purposes of 20 CSR 2220-6.060 to 20 CSR 2220-6.080, modification shall include selecting a new, different, or additional medication or device, discontinuing a current medication or device, or selecting a new, different, or additional strength, dose, dosage form, dosage schedule, or route of administration for a current medication or device, and implementing such selection(s). Medication therapy services shall not include the sole act of dispensing a drug or device pursuant to a valid prescription for the product, generic substitutions made pursuant to section 338.056, RSMo, or medication therapy management that does not include the initiation or implementation of a modification of medication therapy, as provided herein;

(E) Pharmacy resident – A Missouri-licensed pharmacist enrolled in a residency training program accredited by the American Society of Health-System Pharmacists or a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists;

(F) Prescription order for medication therapeutic plan – A lawful order that is issued by the authorizing physician within the scope of his/her professional practice for the provision of medication therapy services by a pharmacist for a specific patient, including, patients of a health care entity; and

(G) Protocol – A medication therapy protocol, as defined herein.

(2) The provisions of 20 CSR 2220-6.060 to 20 CSR 2220-6.080 and 20 CSR 2150-5.026 to 20 CSR 2150-5.028 shall only be deemed applicable to persons or entities under the jurisdiction of the Missouri State Board of Pharmacy and the Missouri State

Board of Registration for the Healing Arts, as established by Chapter 338, RSMo, and Chapter 334, RSMo.

AUTHORITY: sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011. Original rule filed Jan. 13, 2012, effective Aug. 30, 2012.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.380, RSMo 2007.*

20 CSR 2220-6.070 Certificate of Medication Therapeutic Plan Authority

PURPOSE: This rule establishes procedures for obtaining a certificate of medication therapeutic plan authority, as authorized by section 338.010, RSMo.

(1) A pharmacist shall obtain a certificate of medication therapeutic authority from the Missouri State Board of Pharmacy to provide medication therapy services that include initiating or implementing a modification of a patient's medication therapy or device usage. Pharmacists with a certificate of medication therapeutic authority shall enter into a written protocol with a Missouri-licensed physician that complies with the requirements of 20 CSR 2220-6.080, prior to performing medication therapy services.

(2) Applicants for certification shall hold an active Missouri pharmacist license. Applications shall be submitted on forms provided by the Missouri State Board of Pharmacy and shall be accompanied by the certificate of medication therapeutic plan authority fee and proof the applicant –

(A) Holds a doctor of pharmacy (PharmD) degree earned from a school, accredited by the Accreditation Council for Pharmacy Education (ACPE); or

(B) Has successfully completed a post-graduate medication therapy certificate course or program accredited or granted by the APCE, American Society of Health-System Pharmacists, American Society of Consultant Pharmacists, or the American Pharmacists Association; or

(C) Holds a current certification from the Board of Pharmaceutical Specialties, the Commission for Certification in Geriatric Pharmacy, or the National Certification Board for Diabetes Educators; or

(D) Has completed a post-graduate medication therapy certificate course that, at a minimum, included training in the following areas:

1. Assessing patient specific data and issues;
2. Establishing medication therapeutic goals or medication related action plans for identified medication conditions and medication related concerns;
3. Assessing and addressing adverse reactions and adverse drug events;
4. Modifying and monitoring medication regimens;
5. Improving patient care and outcomes through medication therapy services;
6. Evaluating treatment progress;
7. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in medication regimen reviews;
8. Medication reconciliation;
9. Drug utilization review;
10. Applicable state or federal law;
11. Formulating and documenting personal medication records;
12. Documenting clinical outcomes;
13. Interpreting, monitoring, ordering, and assessing patient test results; and
14. Patient education and counseling.

(3) Certificate Renewal. A certificate of medication therapeutic plan authority shall be renewed biennially with the certificate holder's Missouri pharmacist license. For purposes of renewal, six (6) of the continuing education hours required for renewing the certificate holder's Missouri pharmacist license shall be earned in courses/programs related to medication therapy management. The continuing education required by this rule shall be governed by the rules of the Missouri State Board of Pharmacy governing pharmacist continuing education.

(4) The Missouri State Board of Pharmacy may discipline or terminate a pharmacist's certificate of medication therapeutic plan authority if the Missouri State Board of Pharmacy determines that the pharmacist has violated the terms of a protocol, the requirements of Chapter 338, RSMo, or rules of the board governing medication therapy services or any other state or federal drug law.

AUTHORITY: sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011. Original rule filed Jan. 13, 2012, effective Aug. 30, 2012.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.380, RSMo 2007.*

20 CSR 2220-6.080 Medication Therapy Services By Protocol

PURPOSE: This rule establishes procedures for the provision of medication therapy services by protocol, as authorized by section 338.010, RSMo.

(1) Except as otherwise provided herein, a pharmacist who holds a certificate of medication therapeutic plan authority from the Missouri State Board of Pharmacy shall be authorized to provide medication therapy services in Missouri if the pharmacist –

(A) Holds a current Missouri pharmacist license that is not under discipline with the Missouri State Board of Pharmacy; and

(B) Has entered into a written protocol with a Missouri licensed physician that complies with the requirements of this rule.

(2) General Requirements. A pharmacist may provide medication therapy services only with current certification and as authorized by the protocol and the authorizing physician. A pharmacist providing medication therapy services pursuant to this rule shall comply with the following:

(A) Prior to providing medication therapy services, the pharmacist shall receive a prescription order for a medication therapeutic plan from the authorizing physician for a specific patient which authorizes the pharmacist to perform medication therapy services. Except as otherwise provided in subsection (2)(B) of this rule, the prescription order for a medication therapeutic plan shall be valid for no more than one (1) year and shall include:

1. The patient's name, address, and date of birth;
2. The date the prescription order for a medication therapeutic plan is issued;
3. The clinical indication for medication therapy services;
4. The length of time for providing medication therapy services, if less than one (1) year; and

5. The authorizing physician's name and address;

(B) A prescription order for a medication therapeutic plan may be transmitted orally, electronically, or in writing. If an oral prescription order for a medication therapeutic plan is issued, all information required under subsection (2)(A) of this rule shall be documented by the pharmacist and maintained in the patient's record in accordance with section (7) of this rule;

(C) The pharmacist shall review relevant prescription records, patient profiles, patient medical records, or other medical information to determine the services to be rendered; and

(D) In lieu of compliance with 20 CSR 2220-2.018, prescription orders for medication therapy services shall comply with the provisions of this rule, provided the pharmacist shall maintain the prescription order in the patient record required by section (7) of this rule and shall document any change or alteration made to the prescription ordered based on contact with the prescriber in the applicable patient record.

(3) Authorizing Physician Requirements.

(A) The authorizing physician shall be actively engaged in the practice of medicine in the state of Missouri and shall hold a current and unrestricted Missouri physician license pursuant to Chapter 334, RSMo.

(B) The authorizing physician shall be responsible for the oversight of the medication therapy services provided by the pharmacist that are authorized by protocol. The authorizing physician shall also consider the level of skill, education, training, and competence of the pharmacist and ensure that the activities authorized by the protocol are consistent with the pharmacist's level of skill, education, training, and competence.

(C) The written protocol shall be reviewed and signed by the pharmacist and the authorizing physician at least annually and revised as needed. The authorizing physician and pharmacist shall document the date of the annual review on the written protocol.

(D) The authorizing physician shall review the pharmacist's medication therapy service activities regularly, but not less than once every three (3) months. If the pharmacist is providing medication therapy services for, or on behalf of, a health care entity, the review requirements shall be satisfied if the pharmacist's work and services are reviewed every three (3) months by a clinical care committee, pharmacy and therapeutics committee, or a reviewing body/committee of the health care entity that includes a Missouri-licensed physician. The review required by this subsection may be accomplished in person or by electronic means.

(E) The practice location of the authorizing physician shall be no further than fifty (50) miles by road from the pharmacist identified in the written protocol.

(F) An authorizing physician shall notify the Missouri State Board of Registration for the Healing Arts of a written protocol for medication therapy services entered with a pharmacist at each renewal of the authorizing physician's license.

(4) Protocol Requirements.

(A) The medication therapy services performed by a pharmacist pursuant to the protocol shall be within the authorizing physician's scope of practice and within the skill, education, training, and competence of both the authorizing physician and the pharmacist.

(B) The written protocol between the authorizing physician and pharmacist shall, at a minimum, include the following:

1. The identity and signatures of the authorizing physician and pharmacist;

2. The effective dates of the protocol;

3. A statement of clinical conditions, diagnoses, diseases, and specific drugs, or drug categories included in the written protocol and the type of medication therapy services allowed in each case;

4. A statement of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting medication therapy services;

5. Procedures for documenting medication therapy decisions made by the pharmacist and a plan for communication, feedback, and reporting to the authorizing physician concerning specific decisions made;

6. A mechanism and procedure that allows the authorizing physician to override, rescind, modify, or otherwise amend the protocol. All modifications or amendments to the protocol shall be documented in writing, signed, and dated by all involved parties prior to the implementation of such modification or amendment. The protocol may be immediately rescinded by the authorizing physician or the pharmacist with or without cause, provided the rescission is documented in writing. If any conflict arises regarding the professional judgment of the pharmacist and physician with regard to the subject of the medication therapy services, the physician has ultimate authority;

7. A statement that the pharmacist shall not delegate the responsibility of medication therapy services to another person;

8. A description of any authority granted to the pharmacist to administer any drug or medication including the identification of any such drug, medication, or device;

9. A description of drug therapy related patient assessment procedures or testing that may be ordered or performed by the pharmacist, including any authority to order or perform routine or other laboratory testing;

10. Provisions for allowing the pharmacist to access the patient's medical records for purposes of providing medication therapy services;

11. A provision for providing the authorizing physician access to patient records for medication therapy services provided by the pharmacist for patients of the authorizing physician;

12. Provisions establishing a course of action the pharmacist is authorized to follow to address emergency situations, including, but not limited to, anaphylactic or other adverse medication reactions, adverse needle sticks, or other adverse events;

13. Criteria for timely communication from the authorizing physician to the pharmacist and from the pharmacist to the authorizing physician, not inconsistent with the provisions of this rule;

14. The notification requirements required by section (5) of this rule; and

15. The method for reviewing the pharmacist's medication therapy work or services by the authorizing physician, as required by subsection (3)(D) of this rule.

(C) The written protocol shall include a description of medication therapy services the pharmacist is authorized to render or provide. Such services may include:

1. Assessing patient-specific data and issues;

2. Establishing medication therapeutic goals or medication related action plans for identified medical conditions and medication related concerns;

3. Assessing and addressing adverse reactions and adverse drug events;

4. Modifying and monitoring medication regimens;

5. Evaluating treatment progress;

6. Assessing and monitoring pharmacokinetic and pharmacodynamic changes in medication regimen reviews;

7. Medication reconciliation;

8. Drug utilization review;

9. Formulating and documenting personal medication records;

10. Documenting clinical outcomes;

11. Interpreting, monitoring, and assessing patient test results;

12. Initiation of drug therapy, as authorized by protocol; and

13. Patient education and counseling.

(D) The protocol required by this section shall be signed and dated by the authorizing physician and the pharmacist. If the protocol includes multiple authorizing physicians or participating pharmacists, a separate protocol shall not be required for each physician or pharmacist if all authorizing physicians and pharmacists have signed and dated a statement agreeing to be governed by the terms of the written protocol.

(E) Any revisions, modifications, or amendments to the protocol must be in writing. The authorizing physician shall promptly notify the pharmacist of any such revision, modification, or amendment and shall maintain documentation of the notification, including the date such notification was made. The authorizing physician may delegate the notification requirements of this subsection to an authorized designee, provided the physician shall be ultimately responsible for compliance with the notification requirements.

(F) A pharmacist shall not be authorized to adjust, change, or modify any controlled substance prescribed for a patient, except as authorized by state or federal law.

(G) The protocol shall be maintained by the authorizing physician and the pharmacist for a minimum of eight (8) years after termination of the protocol. The protocol may be maintained electronically.

(H) A protocol shall automatically and immediately terminate if the pharmacist ceases to maintain an active Missouri pharmacist license, the authorizing physician is deceased, or if the authorizing physician fails to maintain an active, unrestricted Missouri physician license.

(I) Pharmacy Residents. If specifically authorized by the protocol, a pharmacy resident shall be authorized to perform medication therapy services under the written protocol of a Missouri pharmacist in lieu of an individual protocol, if –

1. The resident holds a certificate of medication therapeutic plan authority from the Missouri State Board of Pharmacy;

2. The resident is enrolled in a residency training program accredited by the American Society of Health-System Pharmacists or a residency training program with a valid application for accreditation pending with the American Society of Health-System Pharmacists; and

3. The resident is providing medication therapy services under the supervision of a Missouri pharmacist certified by the Missouri State Board of Pharmacy to perform medication therapy services.

(J) The provisions of subsection (4)(I) shall only apply to medication therapy services provided by a pharmacist as part of his/her residency training.

(5) Notification Requirements. A pharmacist shall comply with the following notification requirements:

(A) Within twenty-four (24) hours after learning of an anaphylactic or other adverse medication reaction, adverse needle stick, or other adverse event experienced by a patient, the pharmacist shall notify the patient's authorizing physician or an authorized designee of the authorizing physician;

(B) The pharmacist shall notify the authorizing physician or an authorized designee of the authorizing physician in the written protocol of any modification of therapy, within twenty-four (24) hours, provided the protocol may include more stringent notification requirements;

(C) A pharmacist shall be deemed in compliance with the notification requirements of this rule if the pharmacist is providing medication therapy services for, or on behalf of, a health care entity, as defined by this rule, and documentation of the notifications required by this section is recorded in a patient medical record that is required to be maintained by the health care entity pursuant to state or federal law; and

(D) Notifications required by this section shall be in writing unless otherwise authorized by the authorizing physician.

(6) Modifying Drug Therapy.

(A) A pharmacist may be authorized by protocol to modify a patient's non-controlled substance medication therapy, subject to the following:

1. If the pharmacist modifies medication therapy and a medication or device is to be dispensed, the pharmacist shall create a prescription for the medication or device modified under the authorizing physician's name. Such prescription may be dispensed by a licensed pharmacy and shall be maintained in the prescription records of the dispensing pharmacy as provided by the rules of the Missouri State Board of Pharmacy; and

2. If the pharmacist modifies medication therapy or a device, the pharmacist shall document such modification according to section (7) of this rule. Pharmacists providing medication therapy services for patients of a health care entity shall be deemed in compliance with the provisions of this subsection if the modification is documented in a patient medical record that the health care entity is required to maintain under state or federal law.

(B) The pharmacist shall not modify any controlled substance prescription. A prescription from the authorizing physician shall be required to modify a controlled substance.

(C) For purposes of 20 CSR 2220-6.060, 20 CSR 2220-6.070, and 20 CSR 2220-6.080, modification of medication therapy shall include selecting a new, different, or additional medication or device, discontinuing a current medication or device, or selecting a new, different, or additional strength, dose, dosage form, dosage schedule, or route of administration for a current medication or device, and implementing such selection(s). Medication therapy services shall not include the sole act of dispensing a drug or device pursuant to a valid prescription for the product or generic substitutions made pursuant to section 338.056, RSMo.

(7) Record Keeping.

(A) A pharmacist shall document and maintain an adequate patient record of medication therapy services provided to each patient. The records may be maintained in electronic format provided the records are capable of being printed for review by the Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy. An adequate and complete patient record shall include documentation of the following:

1. The identification of the patient, including, name, birthdate, address, and telephone number;

2. The date(s) of any patient visit or consultation, including the reason for any such visit/consultation;

3. Any pertinent assessments, observations, or findings;

4. Any diagnostic testing recommended or performed;

5. The name of any medication or device modified and the strength, dose, dosage schedule, dosage form, and route of administration of any medication modified or administered;

6. Referrals to the authorizing physician;

7. Referrals for emergency care;

8. Any contact with the authorizing physician concerning the patient's treatment or medication therapy services plan;

9. Any informed consent for procedures, medications, or devices; and

10. Any consultation with any other treatment provider for the patient and the results of such consultation.

(B) Pharmacist Record Retention. Except as otherwise provided herein, records required to be maintained by a pharmacist pursuant to this rule shall be maintained securely and confidentially for a minimum of seven (7) years after termination of the protocol unless more stringent requirements are established for record keeping under state or federal law. All records required to be maintained by the pharmacist by this rule shall be maintained by the pharmacist at an address that shall be identified in the written protocol.

(C) Physician Record Retention. Except as otherwise provided herein, records required to be maintained by the authorizing physician pursuant to this rule shall be maintained securely and confidentially for a minimum of seven (7) years after termination of the protocol unless more stringent requirements are established for record keeping pursuant to state or federal law.

(8) Production of Records. Records maintained at a pharmacy must be produced during an inspection or investigation by the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, or their authorized representatives, as requested by the respective board or the board's designee. Records not maintained at a pharmacy shall be produced within three (3) business days after a request from the Missouri State Board of Pharmacy, Missouri State Board of Registration for the Healing Arts, and/or its authorized representative. Failure to maintain or produce records as provided by this rule shall constitute grounds for discipline.

(9) Nothing in this rule shall be construed to permit medical diagnosis of any condition by a pharmacist or the independent issuing of a prescription by a pharmacist.

(10) A pharmacist shall not violate or practice in a manner inconsistent with the provisions of this rule or a written protocol. A pharmacist's failure to abide by the requirements of this rule or the provisions of a written protocol shall be subject to disciplinary action pursuant to the provisions of Chapter 338, RSMo.

(11) The requirements of this rule shall not apply to the administration of vaccines pursuant to protocol as governed by 20 CSR 2220-6.050 or the administration of medication by protocol as governed by 20 CSR 2220-6.040.

(12) The Missouri State Board of Registration for the Healing Arts and the Missouri State Board of Pharmacy separately retain the right and duty to discipline their respective licensees for violations of any state or federal statutes, rules, or regulations regardless of the licensee's participation in a protocol agreement.

(13) The provisions of 20 CSR 2220-6.060 to 20 CSR 2220-6.080 and 20 CSR 2150-5.026 to 20 CSR 2150-5.028 shall only be deemed applicable to persons or entities under the jurisdiction of the Missouri State Board of Pharmacy and the Missouri State Board of Registration for the Healing Arts, as established by Chapter 338, RSMo, and Chapter 334, RSMo.

AUTHORITY: sections 338.010, 338.140.1., and 338.380, RSMo Supp. 2011. Original rule filed Jan. 13, 2012, effective Aug. 30, 2012.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; and 338.380, RSMo 2007.*

20 CSR 2220-6.100 Pharmacy Standards for Dispensing Blood-Clotting Products

PURPOSE: This rule implements the provisions of section 338.400, RSMo, and establishes pharmacy standards for dispensing blood-clotting products.

(1) Definitions. The following definitions are hereby adopted and applicable to this rule:

(A) "Bleeding disorder," a medical condition characterized by a deficiency or absence of one (1) or more essential blood-clotting components in the human blood, including all forms of hemophilia, acquired hemophilia, von Willebrand's disease, and other bleeding disorders that result in uncontrollable bleeding or abnormal blood-clotting. As defined by section 338.400, RSMo, "bleeding disorder" does not include a bleeding condition secondary to another medical condition or diagnosis, except for acquired hemophilia;

(B) "Blood-clotting product," a medicine approved for distribution by the federal Food and Drug Administration (FDA) that is used for the treatment and prevention of symptoms associated with bleeding disorders, including, but not limited to, recombinant and plasma derived factor products, von Willebrand factor products, antifibrinolytics, bypass products for patients with inhibitors, prothrombin complex concentrates, and activated prothrombin complex concentrates. Except as otherwise provided by section 338.400, RSMo, a "blood-clotting product" does not include medical products approved solely for the treatment or prevention of side effects of a blood-clotting drug or medication;

(C) "Established patient," For purposes of section 338.400, RSMo, and this rule, an "established patient" shall be defined as a bleeding disorder patient that has been dispensed a legend blood-clotting product by the pharmacy on more than three (3) occassions in a single calendar year; and

(D) "Pharmacy," an entity engaged in the practice of pharmacy as defined in section 338.100, RSMo, that provides blood-clotting products and ancillary infusion equipment or supplies to patients with bleeding disorders.

(2) General Requirements. All Missouri licensed pharmacists and pharmacy permit holders shall comply with the following requirements when dispensing blood-clotting factor concentrates:

(A) Prescriptions for blood-clotting factor concentrates shall be dispensed as written or authorized by the prescribing physician, in accordance with state and federal law. No changes or substitutions shall be made unless approved by the prescriber. If the pharmacy has received prescriber authorization to change or substitute the blood-clotting factor concentrate originally prescribed, the patient or the patient's designee shall be notified and counseled regarding the change or substitution prior to dispensing via the preferred contact method identified by the patient or designee pursuant to subsection (2)(E);

(B) If requested by the patient or the patient's designee, the pharmacy shall ship and deliver blood-clotting factor

concentrates to the patient or the patient's designee as prescribed within two (2) business days of receiving a prescription or refill request for established patients and three (3) business days for new patients in nonemergency situations. Nonemergency situations shall include, but may not be limited to, routine prophylaxis requests. Appropriate cold chain management and packaging practices must be used to ensure proper drug temperature, stability, integrity, and efficacy are maintained during shipment in accordance with manufacturer requirements;

(C) Patients must be provided with a designated pharmacy contact telephone number for reporting problems with a delivery or product on each dispensing at no cost to the patient;

(D) Unless otherwise authorized by the patient or the patient's designee, the pharmacy shall contact the patient for authorization to dispense prior to shipping a refill of any blood-clotting product to the patient. The date of patient authorization shall be documented in the pharmacy's prescription records;

(E) Barring extenuating circumstances, prescriptions for blood clotting factor concentrates shall be dispensed within plus or minus ten percent (10%) of prescribed assays, or as otherwise authorized or directed by the prescriber; and

(F) Recalls or Withdrawals. Prior to dispensing any blood clotting factor concentrate, the pharmacy shall ask the patient or the patient's designee to designate a preferred contact method for receiving notifications in the event of a recall or withdrawal of the concentrate dispensed or any related ancillary infusion equipment and supplies dispensed by the pharmacy. The preferred contact method shall be documented with the patient information required by 20 CSR 2220-2.190(2).

1. Notice of concentrate or ancillary infusion equipment and supplies recalls and withdrawals shall be provided to the patient via the patient's preferred contact method within twenty-four (24) hours of receipt of a recall or withdrawal notification from the manufacturer or any state or federal entity that requires or recommends patient notification. The pharmacy shall also notify the prescribing physician within twenty-four (24) hours of such recall or withdrawal and shall obtain a prescription for an alternative product if a new or amended prescription is required to dispense or deemed necessary and appropriate by the prescriber.

2. If attempts to contact the patient via the preferred contact method are unsuccessful, the pharmacy shall mail notification to the patient or the patient's authorized designee within the required twenty-four (24) hours or the next business day.

3. The time, date, and method of notification to the patient and prescriber shall be documented in the pharmacy's records and maintained for two (2) years from the date of recall or withdrawal.

(3) In addition to the provisions of section (2), pharmacies that dispense blood-clotting products to established patients, or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients, shall comply with the following standards of care:

(A) The pharmacy shall annually notify the board in writing of the pharmacy's intent to provide legend blood-clotting products for bleeding disorder patients. Notification shall be made on or before January 31 of each calendar year in a manner and form approved by the board;

(B) The pharmacy shall identify in advance, or make arrangements with, a supplier or suppliers capable of providing all brands, assays, and vial sizes of blood-clotting products approved by the federal FDA, including products manufactured from human plasma and those manufactured from recombinant technology techniques. A list of all designated or identified suppliers shall be maintained at the pharmacy and made available during inspection. This requirement shall not be construed to require a pharmacy to purchase products prior to receiving a valid prescription order;

(C) A pharmacist shall be available twenty-four (24) hours a day, seven (7) days a week, every day of the year, either onsite or on call, to fill prescriptions for blood-clotting products, within the time frames designated by section 338.400, RSMo, and the provisions of this rule;

(D) Pharmacists engaged in dispensing or filling blood-clotting factor concentrates or who provide patient counseling regarding blood-clotting factor concentrates to bleeding disorder patients shall have sufficient knowledge, experience, and training to perform the duties assigned. To ensure continued competency, pharmacists engaged in counseling bleeding disorder patients shall complete four (4) continuing education hours (0.40 CEU) related to blood-clotting factor concentrates, infusion treatment or therapy, or blood-clotting disorders or diseases each biennial renewal period. The continuing education required by this rule may be used to satisfy the pharmacist's continuing education requirements. Proof of compliance with this section shall be maintained at the pharmacy for a minimum of four (4) calendar years and shall be made available during inspection or at the request of the board;

(E) If requested by the patient or the patient's designee, the pharmacy shall provide for the shipment and delivery of blood-clotting products to the patient or the patient's designee as prescribed within two (2) business days of receiving a prescription or refill request for established patients and three (3) business days for new patients in nonemergency situations;

(F) Established patients shall be provided access to blood-clotting products within twelve (12) hours of notification from a physician of the patient's emergent need for a blood-clotting product. For purposes of this section, determination of an emergent need shall be within the professional medical judgment of the physician. Emergent need requests shall be documented in the pharmacy's prescription records;

(G) The pharmacy shall provide or have available for purchase containers for the disposal of hazardous waste, including, but not limited to, sharp or equivalent biohazard waste containers;

(H) At a minimum, the pharmacy shall provide or have available for purchase ancillary equipment and supplies required to infuse a blood-clotting therapy product into a human vein, including, syringes, needles, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, and cold compression packs. If supplies are depleted, the pharmacy shall restock the required ancillary equipment and supplies in a reasonable amount of time which shall not exceed seven (7) calendar days;

(I) The pharmacy shall have contact information available for a nurse or nursing service or agency with experience in providing infusion related nursing services or nursing services for bleeding disorder patients if such services are not provided by the pharmacy;

(J) If requested by the patient or the patient's authorized designee, the pharmacist shall explain any known insurance copayments, deductibles, coinsurance payments, or lifetime maximum insurance payment limits. For purposes of complying with this section, the pharmacy may rely on information supplied by the patient's insurer; and

(K) The pharmacy shall register with the National Patient Notification System, or its successor, to receive recall notification for all products included in the National Patient Notification System. The pharmacy shall maintain current and accurate contact information with the National Patient Notification System.

(4) Pharmacies that provide legend blood-clotting products to treat or prevent symptoms of established bleeding disorder patients, or that offer or advertise to provide blood-clotting products specifically for bleeding disorder patients, shall develop and follow written policies and procedures to ensure compliance with section 338.400, RSMo, and the provisions of this rule. The pharmacy shall review the policies and procedures on an annual basis and document such review. At a minimum, the pharmacy's written policies and procedures must include procedures for:

(A) Processing prescriptions for blood-clotting products by pharmacy staff to ensure the timely handling and dispensing of blood-clotting products;

(B) Processing partial fill requests by patients to reduce or eliminate excessive dispensing;

(C) Providing and documenting recall notifications in accordance with this rule;

(D) Transferring, dispensing, refilling, or delivering blood-clotting factor concentrates to established patients in the event of an emergency or disaster;

(E) Notifying patients prior to terminating business or terminating the dispensing of any blood-clotting factor concentrate or prior to a known or an anticipated termination of pharmacy services for a bleeding disorder patient. Notification shall be provided in writing and, when reasonably possible, shall be provided a minimum of seven (7) days prior to any such termination;

(F) Shipping or providing blood-clotting products to the patient within the time frames required herein;

(G) Receiving, processing, and dispensing prescription or dispensing requests for a blood-clotting product to bleeding disorder patients, including procedures for handling and processing physician request indicating a patient's emergent need for a blood-clotting product;

(H) Ensuring appropriate cold chain management and packaging practices are used to ensure proper drug temperature, stability, integrity, and efficacy are maintained during shipment in accordance with manufacturer requirements; and

(I) Handling and processing preauthorization notifications and requests and communicating preauthorization requirements to the patient and applicable prescriber.

(5) This rule shall not be construed to require dispensing without appropriate payment or payment arrangements. If the pharmacy is waiting for authorization, certification, or other action from a third-party payer prior to dispensing, the pharmacy shall notify the patient that the prescription is available for dispensing and explain any alternative payment options. Notification shall be provided as soon as reasonably practicable. At a minimum, however, notification shall be provided to the patient prior to the expiration of the shipping and delivery time frames required by subsection (2)(E), (3)(B), or (3)(F) of this rule.

AUTHORITY: section 338.280, RSMo 2000, and sections 338.140 and 338.400, RSMo Supp. 2012. Original rule filed Nov. 13, 2012, effective May 30, 2013.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.280, RSMo 1951, amended 1971, 1981; and 338.400, RSMo 2011.*

20 CSR 2220-6.200 Pharmacist Authority to Prescribe Pursuant to Section 338.665

PURPOSE: This rule establishes requirements for pharmacists prescribing as authorized by section 338.665, RSMo.

(1) Definitions.

(A) A nicotine replacement therapy product; as defined by section 338.665, RSMo.

(2) Training. Pharmacists prescribing must be competent to perform the services provided and shall maintain ongoing/continued competency.

(3) Pharmacist prescribing and patient care activities must be safely and properly performed.

(A) Pharmacists shall collect patient or medical history to allow the pharmacist to properly assess the patient and safely provide patient care. Prior to prescribing, the pharmacist shall use a screening procedure based on generally accepted clinical guidelines to identify appropriate patients for treatment. The pharmacist shall refer high-risk patients or patients with a contraindication to the patient's primary care provider or an appropriate healthcare provider, as deemed necessary or appropriate.

(B) In addition to this rule, pharmacists shall comply with all applicable provisions of Chapter 338, RSMo, and the rules of the Board of Pharmacy governing prescribing and record-keeping, including, but not limited to, 20 CSR 2220-2.018. Pharmacists may provide a prescription to the patient or transmit a prescription for that patient to a pharmacy for dispensing.

(4) Patient medical records. Prescribing pharmacists shall maintain an adequate and complete patient medical record for each patient that documents the care provided. Patient medical records must be individually retrievable.

(A) At a minimum, the required patient medical record must include:

1. The patient's name, birthdate, address and telephone number;
2. The date(s) the patient was seen;
3. The patient's primary care provider, if provided;
4. Documentation of the patient screening as required by section (3) of this rule;
5. Any pertinent medical or medication information/history;
6. The name and dosage of any medication prescribed;
7. Any recommended medication treatment plan(s) or follow-up consultation(s); and
8. Any healthcare provider referrals.

(B) Patient medical records must be securely and confidentially maintained in compliance with applicable state and federal law. At a minimum, patient medical records must be maintained for five (5) years from the date created. Records maintained at a pharmacy must be produced immediately or within two (2) hours of a request from the board or the board's authorized designee. Records not maintained at a pharmacy must be produced within three (3) business days of a board request.

AUTHORITY: sections 338.010, 338.140, and 338.665, RSMo Supp.

2019. Original rule filed March 9, 2020, effective Oct. 30, 2020.*

**Original authority: 338.010, RSMo 1939, amended 1951, 1989, 1990, 2007, 2009, 2011, 2014, 2017, 2018, 2019; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.665, RSMo 2019.*

20 CSR 2220-7

TITLE 20 – DEPARTMENT OF COMMERCE AND INSURANCE
Division 2220 – State Board of Pharmacy
Chapter 7 – Licensing

20 CSR 2220-7.010 General Licensing Rules

PURPOSE: This rule defines terms used and general requirements governing board licensing activities as used in Chapter 7.

(1) Definitions.

(A) ACPE – Accreditation Council for Pharmacy Education.

(B) Accredited school/college of pharmacy – a school or college of pharmacy accredited by ACPE and located in a U.S. state or territory.

(C) Approved school/college of pharmacy – a Missouri school or college of pharmacy whose curriculum, physical equipment, course of instruction, and teaching personnel conform to ACPE standards and specifications and that has been recognized by the board as an approved school/college for pharmacy practice experience pursuant to 20 CSR 2220-7.027.

(D) Board – the Missouri State Board of Pharmacy.

(E) Foreign school/college – a school/college of pharmacy that is not located in the United States or a United States territory.

(F) MPJE – Multistate Pharmacy Jurisprudence Examination.

(G) NABP – National Association of Boards of Pharmacy.

(H) NAPLEX – North American Pharmacist Licensure Examination.

(2) An application shall not be considered filed if it has to be returned to the applicant for an incorrect or missing fee, an incomplete or missing college affidavit, or an incomplete or missing signature or notarization. In this instance, the application will be returned to the applicant and will not be deemed filed until it has been returned with all corrections made. A pharmacist license application shall be deemed invalid if the applicant fails to submit or make available via NABP all information required to complete the application within ninety (90) days after the application is received by the board, with the exception of NAPLEX or MPJE examination scores.

(3) No duplicate license, certificate, or registration shall be issued until the duplicate license fee has been paid and the most recent license, registration, or certificate has been returned to the board office or the licensee/registrant/certificate holder submits an attestation under penalty of perjury that the license, certificate, or registration has been lost, stolen, or destroyed.

(4) Except as otherwise provided, all licensing and registration fees required by the rules of the board are nonrefundable.

(5) A copy of proof of licensure/registration from the board's official website may be used as proof of licensure by an applicant until a hard copy license/registration has been received from the board.

(6) Failure to receive a renewal notice or application from the board shall not excuse the licensee/registrant from any renewal requirements established by Chapter 338, RSMo, or by rule of the board.

(7) Except as otherwise determined by the board, a pharmacist applicant shall be eligible for a temporary authorization letter to practice pharmacy pending final board approval of the applicant's pharmacist license if the applicant has submitted a complete pharmacist application to the board and has successfully passed all required examinations (NAPLEX and/or MPJE).

(A) Applicants not eligible for a temporary authorization letter may apply for a technician registration pursuant to the rules of the board. Applicants working as a technician shall be under the direct supervision of a licensed pharmacist at all times when any functions related to section 338.010, RSMo, are performed and shall comply with all Missouri requirements for pharmacy technicians.

(B) Applicants required to apply for a technician registration will not be required to provide fingerprints if all fingerprinting requirements have previously been fulfilled and the fingerprints were submitted less than six (6) months before the board's receipt of the application for technician registration.

AUTHORITY: sections 338.020, 338.030, 338.040, 338.043, 338.070, and 338.280, RSMo 2016, and section 338.140, RSMo Supp. 2022. Original rule filed Jan. 10, 2013, effective Aug. 30, 2013. Amended: Filed May 31, 2022, effective Nov. 30, 2022.*

**Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990, 2014; 338.030, RSMo 1939, amended 1949, 1951, 1981, 1990, 2001; 338.040, RSMo 1939, amended 1961, 1969, 1981, 1990; 338.043, RSMo 1990, amended 1997, 2001; 338.070, RSMo 1939, amended 1947, 1953, 1961, 1969, 1981, 1985, 1997; 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019; and 338.280, RSMo 1951, amended 1971, 1981.*

20 CSR 2220-7.025 Intern Pharmacist Licensure

PURPOSE: This rule establishes requirements for intern pharmacist licensure and pharmacy practice experience.

(1) The provisions of this rule shall be applicable to individuals seeking to earn pharmacy practice experience in Missouri.

(2) Requirements for Licensure. Every person who desires to gain pharmacy practice experience in Missouri shall first apply for an intern pharmacist license. Application for licensure shall be made on forms provided by the board and shall be accompanied by the application fee. To be eligible for licensure, the applicant shall submit proof of fingerprinting as required by 20 CSR 2220-7.090 and must be –

(A) Currently enrolled in or graduated from a school or college of pharmacy that is accredited by the Accreditation Council for Pharmacy Education (ACPE); or

(B) A graduate of an ACPE accredited school or college of pharmacy who is actively seeking to earn pharmacy practice experience to qualify for Missouri pharmacist licensure; or

(C) A graduate of a foreign school/college of pharmacy as defined by 20 CSR 2220-7.040 who has obtained Foreign Graduate Equivalency Certification from the National Association of Boards of Pharmacy and is actively seeking to earn pharmacy practice experience to qualify for Missouri licensure.

(3) Site/Preceptor Approval. After licensure, an intern pharmacist shall only be authorized to earn pharmacy practice experience in a site approved by the board and under the supervision of a board approved preceptor. Requests for site and preceptor approval shall be submitted on a form provided by the board. The board may request additional information, interview program participants, or complete site inspections before a decision on an application is made. The intern pharmacist will receive confirmation from the board office noting approval of the site and preceptor and a start date after which pharmacy

practice experience may be counted. In no event shall an intern pharmacist be credited for hours earned prior to being licensed by the board as an intern pharmacist.

(A) Site Approval. The board shall only approve a site for pharmacy practice experience if the site holds a pharmacy license from a United States (U.S.) state or territory and such license is not under disciplinary action with the licensing entity.

(B) Special Sites. An individual or entity/facility may petition the board to approve an entity/facility that is not a licensed pharmacy for purposes of intern training as a special site if the pharmacy practice experience to be earned complies with 20 CSR 2220-7.030(1)(A)3. Requests shall be made on a form provided by the board and shall include a detailed description of the pharmacy practice experience to be earned. The board may limit the number of pharmacy practice hours that may be earned at an approved special site.

(C) Preceptor Approval. To be eligible for approval, a supervising preceptor shall hold a pharmacist license from a U.S. state or territory and such license must be active and not under disciplinary action in such U.S. state or territory. An individual/entity may petition the board to approve a preceptor that is not licensed as a pharmacist in a U.S. state or territory on a form provided by the board. The board may, in its discretion, approve a non-pharmacist preceptor if the preceptor is sufficiently qualified to train interns in the proposed pharmacy practice experience area(s) and the experience to be earned complies with the provisions of 20 CSR 2220-7.030(1)(A)3. The board may limit the amount of pharmacy practice hours that can be earned with a non-pharmacist preceptor.

(D) Students enrolled in an approved school/college of pharmacy shall be authorized to earn experience as part of their school/college curriculum at any site or with any preceptor approved by the board or the school/college as authorized by 20 CSR 2220-7.027. However, students desiring to earn pharmacy practice experience outside of, or in addition to, the training/experience required as part of the curriculum of an approved school/college of pharmacy (i.e., non-school related summer employment) shall comply with the provisions of this rule for the additional hours earned and shall separately request prior approval by the board of the site/preceptor to be used.

(4) Calculation of Hours. An intern pharmacist shall only be given credit for hours earned in activities related to the practice of pharmacy as determined by the board or connected with pharmaceutical or patient-centered care through the interpretation and evaluation of prescription orders; the compounding, dispensing, and labeling of drugs and devices pursuant to prescription orders; the proper and safe storage of drugs and devices and the maintenance of proper records of them; or consultation with patients and other health care practitioners about the safe and effective use of drugs and devices.

(A) Except as otherwise provided herein, an intern pharmacist shall only receive credit for pharmacy practice experience that is earned after the date of licensure as an intern, at an approved site and under the supervision of an approved preceptor.

(B) Certification of Hours. An intern pharmacist shall file a Preceptor's Affidavit of Internship Hours at the completion of his/her pharmacy practice experience on a form provided by the board. The report shall identify the pharmacy practice experience hours earned at each approved training site and shall be signed by the supervising preceptor. No credit shall be granted for hours not reported to the board. In lieu of the preceptor affidavit, an approved school/college of pharmacy shall certify to the board the pharmacy practice experience earned by each student as part of the required curriculum. Certification shall be submitted by the approved school/college of pharmacy upon the student's graduation or within thirty (30) days after the student is no longer enrolled in the pharmacy school/college.

(C) The board may restrict the number of hours an intern pharmacist may earn per week. An intern pharmacist shall not be credited for hours earned while practicing/working as a pharmacy technician.

(D) The board shall not certify or verify any pharmacy practice experience gained in Missouri unless the pharmacy practice experience complies with the requirements of this rule. Additionally, the board will not verify or certify hours earned by a student if the board does not receive certification from the preceptor or the school/college documenting the hours required by this rule.

(5) Change of Intern Location/Preceptor. Except as provided for students of an approved school/college of pharmacy, an intern pharmacist shall promptly notify the board of a change in intern site/preceptor and shall request approval of the site/preceptor to be used. If approved, the intern pharmacist shall not be credited for hours earned more than ten (10) days prior to the date the approval request is filed with the board. No credit shall be granted for hours earned if the request for site/preceptor approval is subsequently disapproved by the board.

(6) Intern pharmacists shall file an application to renew their intern pharmacist license between October 1 and December 31 of each even-numbered year. Applications shall be made on a form provided by the board and accompanied by the renewal fee. An intern pharmacist license shall not be renewed more than two (2) years after the intern pharmacist's graduation from an ACPE accredited school/college of pharmacy. For graduates of a foreign school/college of pharmacy who have obtained Foreign Pharmacy Graduate Equivalency Certification from the National Association of Boards of Pharmacy, an intern pharmacist license shall not be renewed more than once. The board may approve additional renewals in the event of extraordinary circumstances due to no fault of the intern. An intern pharmacist license shall automatically terminate once the intern is issued a Missouri pharmacist license.

AUTHORITY: sections 338.060 and 338.070, RSMo 2016, and sections 338.035 and 338.140, RSMo Supp. 2020. Original rule filed Jan. 10, 2013, effective Aug. 30, 2013. Amended: Filed Dec. 27, 2019, effective July 30, 2020. ** Amended: Filed Dec. 28, 2020, effective June 30, 2021.*

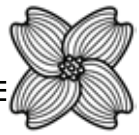
**Original authority: 338.035, RSMo 1990, amended 1993, 1995, 2007, 2020; 338.060, RSMo 1939, amended 1943, 1947, 1949, 1951, 1981, 1984, 1997, 1999; 338.070, RSMo 1939, amended 1947, 1953, 1961, 1969, 1981, 1985, 1997; and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019.*

***Pursuant to Executive Order 21-09, 20 CSR 2220-7.025, subsection (4)(C) was suspended from July 13, 2020 through September 15, 2021.*

20 CSR 2220-7.027 Approved Missouri Schools/Colleges of Pharmacy

PURPOSE: This rule establishes requirements for approval of pharmacy practice experience earned as part of the curriculum of a Missouri school/college of pharmacy.

(1) Upon request, the board may approve a Missouri school/college of pharmacy for purposes of providing pharmacy practice



experience to enrolled students. To be eligible for approval, the school/college of pharmacy must be located in Missouri and shall –

(A) Be accredited by the Accreditation Council for Pharmacy Education (ACPE) and comply with all applicable ACPE standards;

(B) Require as part of the school/college curriculum or training, a minimum of one thousand five hundred (1,500) hours of pharmacy practice experience in activities related to the practice of pharmacy as determined by the board or connected with pharmaceutical or patient-centered care through the interpretation and evaluation of prescription orders; the compounding, dispensing, and labeling of drugs and devices pursuant to prescription orders; the proper and safe storage of drugs and devices and the maintenance of proper records of them; the administration of immunizations; or consultation with patients and other health care practitioners about the safe and effective use of drugs and devices;

(C) Submit a list of all preceptors and sites that were used by the school/college curriculum for pharmacy practice experience within the previous year. The list must be submitted to the board annually for review; and

(D) Submit the school's/college's policies and procedures for obtaining practice experience for board approval. The policies and procedures shall include policies/procedures for student training, approving sites/preceptors, and monitoring practice experience activities.

(2) The board may, in its discretion, disapprove a Missouri school/college of pharmacy if the policies or procedures do not comply with the pharmacy practice experience requirements of this rule or Chapter 338, RSMo. Policies and procedures shall be resubmitted annually to the board for approval or as otherwise requested by the board.

(3) An intern pharmacist shall be authorized to earn pharmacy practice experience required by an approved school's/college's curriculum or training requirement at any site approved by the school/college for pharmacy practice experience, provided the site/preceptor complies with ACPE standards and meets the requirements of 20 CSR 2220-7.025(3). The board expressly reserves the right to disapprove a site/preceptor that does not comply with Chapter 338, RSMo, the rules of the board, or ACPE standards if deemed necessary to ensure proper intern training.

(4) Certification of Hours. An approved school/college shall certify the pharmacy practice experience earned by a student to the board upon the student's graduation or within thirty (30) days after the student is no longer enrolled in the pharmacy program. The board will not verify or certify hours earned by a student as part of the curriculum of a recognized school/college if the board does not receive certification from the school/college documenting the hours earned. An intern pharmacist shall not be granted credit for hours earned while practicing/working as a pharmacy technician.

AUTHORITY: sections 338.020 and 338.030, RSMo 2016, and section 338.140, RSMo Supp. 2019. Original rule filed Jan. 10, 2013, effective Aug. 30, 2013. Amended: Filed Dec. 27, 2019, effective July 30, 2020.*

**Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990, 2014; 338.030, RSMo 1939, amended 1949, 1951, 1981, 1990, 2001; and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019.*

20 CSR 2220-7.030 Pharmacist Licensure by Examination

PURPOSE: This rule establishes licensure requirements for examination applicants that have graduated from an accredited college/school of pharmacy.

(1) Examination Applications.

(A) Graduates of an accredited college/school of pharmacy may apply to the board for licensure as a Missouri pharmacist by examination. Applications shall be submitted on forms provided by the board with the examination application fee. The application must be notarized and include:

1. Satisfactory evidence that the applicant has graduated from an accredited school/college of pharmacy that meets the requirements of this rule;

2. Proof that the applicant has completed a state and federal criminal history background check, as required by 20 CSR 2220-7.090; and

3. Proof of one thousand five hundred (1,500) hours of pharmacy practice experience in activities related to the practice of pharmacy as approved by the board or connected with –

A. Patient-centered pharmaceutical care or pharmacist clinical services;

B. Evaluating or interpreting prescriptions or medication orders;

C. Compounding, dispensing, and labeling of drugs and devices;

D. The proper and safe storage of drugs and devices and appropriate record keeping for them;

E. Medication administration;

F. Medication therapy review/management; and

G. Consulting with patients and other health care practitioners about the safe and effective use of drugs and devices.

(B) Pharmacy practice experience earned in another state must be certified directly to the board from an accredited school/college of pharmacy or the state or governmental pharmacist licensing entity where the hours were earned. Alternatively, the board may, in its discretion, accept proof of graduation and the required pharmacy practice experience hours from National Association of Boards of Pharmacy (NABP). Graduates of an accredited school/college of pharmacy located in a U.S. state or territory shall be deemed compliant with the pharmacy practice experience hours required by this rule and are not required to submit additional proof of pharmacy practice experience, unless otherwise requested by the board or the board's authorized designee.

(C) The board shall review the application and determine the candidate's eligibility to test. Applications shall be deemed incomplete until all requirements of this rule have been met. All application fees are non-refundable.

(2) Test Scheduling. When an application has been completed, the board will notify the applicant and/or NABP if he/she is eligible for the North American Pharmacist Licensure Examination (NAPLEX) and/or the Multistate Pharmacy Jurisprudence Examination (MPJE). If eligible, the applicant shall schedule testing dates for both the NAPLEX and MPJE, as required by the NABP. The applicant must comply with all registration, application, testing, and scheduling requirements established by NABP for the examinations, and payment of any fee(s) required by NABP for scheduling/taking the examination(s).

(A) To avoid forfeiture of eligibility, the applicant must take

the examination(s) within three hundred sixty-five (365) days after having been determined eligible by the board to test. If the applicant does not take the examination within three hundred sixty-five (365) days, the applicant must reapply to the board for examination/licensure and pay the examination application fee again.

(B) A determination by the board that an applicant is eligible for examination does not guarantee that the applicant will be issued a Missouri pharmacist license. The board reserves the right to deny an applicant for licensure that has been approved for examination as authorized by Missouri law.

(3) Testing. Applicants for pharmacist licensure by examination must successfully pass both the NAPLEX and the MPJE. To successfully pass, a minimum score of seventy-five (75) is required for each of the required examinations. Applicants must pass both the NAPLEX and MPJE exams within two (2) years of submitting their application for licensure by examination to the board. Failure to achieve passing scores on both exams in this two (2) year period will result in the license application being rejected as incomplete. The applicant may reapply for licensure and restart the examination process, except as otherwise provided by subsection (4)(A) or other provisions of Missouri law.

(4) Retesting. If an applicant fails to achieve a score of seventy-five (75) on both the NAPLEX and the MPJE, the candidate shall retake and pass the failed examination(s) before a license can be issued. Applicants seeking to retake an examination must file an application for re-examination with the board and pay the examination application fee each time. All examinations are scored independently and may be retaken independently.

(A) The board or its authorized designee shall review and approve any applicant that fails the NAPLEX or MPJE three (3) consecutive times prior to the applicant being declared eligible to retest. A candidate will not be declared eligible to retest under this subsection until approved by the board. In lieu of disapproval, the board may establish a date after which the candidate shall be eligible to retest or may establish additional training or study requirements that must be completed before authorization to retest is granted. Applicants who fail the NAPLEX five (5) times shall not be declared eligible to retake the NAPLEX. Applicants who fail the MPJE five (5) times shall not be declared eligible to retake the MPJE unless otherwise approved by the board for extenuating circumstances.

(B) Application for re-examination must be made on a form provided by the board. Examination/re-examination fees are non-refundable.

AUTHORITY: sections 338.020, 338.040, 338.060, and 338.070, RSMo 2016, and sections 338.035 and 338.140, RSMo Supp. 2022. Original rule filed Jan. 10, 2013, effective Aug. 30, 2013. Amended: Filed May 31, 2022, effective Nov. 30, 2022.*

**Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990, 2014; 338.035, RSMo 1990, amended 1993, 1995, 2007, 2020; 338.040, RSMo 1939, amended 1961, 1969, 1981, 1990; 338.060, RSMo 1939, amended 1943, 1947, 1949, 1951, 1981, 1984, 1997, 1999; 338.070, RSMo 1939, amended 1947, 1953, 1961, 1969, 1981, 1985, 1997; and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019.*

20 CSR 2220-7.040 Foreign Graduates

PURPOSE: This rule establishes licensure requirements for pharmacist applicants who are graduates from a pharmacy school/college not located in the United States or a United States territory.

(1) Definitions.

(A) Foreign school/college – For purposes of this rule, a foreign school/college shall be defined as a school/college of pharmacy that is not located in a United States (U.S.) state/territory.

(B) Preliminary evaluation application – The Application for Preliminary Evaluation of Foreign Pharmacy School Graduate provided by the board for graduates of a foreign school/college.

(2) Applicability. The provisions of this rule are applicable to all graduates of a foreign school/college, including, graduates currently or previously licensed as a pharmacist by another U.S. state/territory. Graduates from a foreign school/college of pharmacy shall comply with the provisions of this rule prior to filing an examination application, an application for pharmacist licensure, or a reciprocity application.

(3) Prior to applying for pharmacist licensure/examination, graduates of a foreign school/college shall first obtain Foreign Pharmacy Graduate Equivalency Certification (FPGEC) from the National Association of Boards of Pharmacy Foundation Foreign Pharmacy Graduate Examination Committee. Potential applicants shall pay all fees and comply with all application/certification procedures required by the National Association of Boards of Pharmacy Foundation Foreign Pharmacy Graduate Examination Committee.

(4) After receiving FPGEC, applicants shall file an application for preliminary evaluation with the board. Applications shall be submitted on a form provided by the board and accompanied by the application fee. The preliminary evaluation application shall include:

(A) A copy of a certificate showing proof of name, date of birth, and place of birth by one (1) of the following methods:

1. Birth certificate;
2. Baptismal certificate; or
3. Notarized statement from an authorized governmental agency.

(B) Documentation of name change, if the name on the credentials supplied for evaluation purposes is different than the name appearing on the application;

(C) Proof of fingerprinting as required by 20 CSR 2220-7.090;

(D) A copy of the applicant's FPGEC certificate;

(E) Proof of U.S. citizenship or, if the applicant is not a U.S. citizen, a copy of current visa, along with a copy of a U.S. employment authorization document such as an Alien Registration Receipt Card, Form I-551 or Employment Authorization Card Form I-688-B, or any other document approved or issued by the U.S. government permitting employment in the U.S.; and

(F) Documentation as required by the board showing proof of one thousand five hundred (1,500) hours of pharmacy practice experience related to the practice of pharmacy or proof that the applicant has maintained an active pharmacist license in another U.S. state/territory for a period of not less than one (1) year. To be eligible for licensure, the one thousand five hundred (1,500) hours of pharmacy practice experience must have been earned in a U.S. state/territory after the date the applicant obtained FPGEC certification. Applicants who have not yet completed the one thousand five hundred- (1,500-) hour experience requirement shall apply for licensure as an intern pharmacist and shall complete the required one thousand five hundred (1,500) hours before the applicant's preliminary evaluation application is approved.

(5) Reciprocity/License Transfer. After the preliminary evaluation application has been approved by the board, graduates of a foreign school/college that are currently licensed in another U.S. state/territory shall be governed by, and shall apply for licensure by license transfer/reciprocity pursuant to, 20 CSR 2220-7.050.

(6) Test Scheduling for Foreign Graduates Applying for Licensure by Examination. When an application has been completed, the board shall notify an applicant if he/she is eligible for the North American Pharmacist Licensure Examination (NAPLEX) and/or Multistate Pharmacy Jurisprudence Examination (MPJE) examinations. The applicant shall schedule test dates for both the NAPLEX and MPJE with the National Association of Boards of Pharmacy (NABP). The applicant shall satisfy all testing and scheduling requirements established by NABP and shall complete any necessary application(s) and payment of fee(s) for scheduling/taking the examination(s).

(A) To avoid forfeiture of eligibility, the applicant must take the examination(s) within three hundred sixty-five (365) days after having been determined eligible for examination by the board. If the applicant does not take the examination within three hundred sixty-five (365) days, the applicant shall be required to reapply to the board for examination/licensure and again pay the examination application fee.

(B) A determination by the board that an applicant is eligible for examination does not guarantee that the applicant will be issued a Missouri pharmacist license. The board reserves the right to deny an applicant for licensure that has been approved to take the required examinations as authorized by Missouri law.

(7) Testing. Applicants for licensure by examination shall successfully pass both the NAPLEX and the MPJE examinations. A minimum score of seventy-five (75) is required for each of the required examinations. Upon approval by the board and successful completion of the NAPLEX and MPJE, the board may issue a pharmacist license to the applicant.

(8) Retesting. If an applicant fails to achieve a score of seventy-five (75) on both the NAPLEX and MPJE, the candidate shall retake and pass the failed examination(s) before a license can be issued. Any applicant who fails to achieve a passing score on either of the examinations shall file an application for reexamination with the board and pay the examination application fee each time. All examinations are scored independently and may be retaken independently.

(A) The board shall review and approve any applicant that fails the NAPLEX or MPJE two (2) consecutive times prior to the applicant being declared eligible to retest. A candidate shall not be declared eligible to retest under this subsection until approved by the board. In lieu of disapproval, the board may establish a date after which the candidate shall be eligible to retest or may establish additional training or study requirements to be completed before authorization to retest is granted.

(B) Application for reexamination shall be made on a form provided by the board. Fees for reexamination shall be non-refundable.

(9) Upon approval by the board and successful completion of the NAPLEX and MPJE, the board shall issue a pharmacist license to the applicant.

(10) A preliminary evaluation application shall be deemed invalid if the applicant fails to submit all information required to complete the application within six (6) months after the application is received by the board. However, a preliminary evaluation application shall not be deemed invalid if the applicant has applied for licensure as a Missouri intern pharmacist to complete the required pharmacy practice experience and has completed all other preliminary application requirements, provided the application shall be deemed void if the applicant fails to complete the required pharmacy practice experience within two (2) years from the date the preliminary evaluation application was initially received by the board.

AUTHORITY: sections 338.020, 338.040, 338.060, and 338.070, RSMo 2000, and sections 338.035 and 338.140, RSMo Supp. 2012. Original rule filed Jan. 10, 2013, effective Aug. 30, 2013.*

**Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990; 338.040, RSMo 1939, amended 1961, 1969, 1981, 1990; 338.060, RSMo 1939, amended 1943, 1947, 1949, 1951, 1981, 1984, 1997, 1999; 338.070, RSMo 1939, amended 1947, 1953, 1961, 1969, 1981, 1985, 1997; 338.035, RSMo 1990, amended 1993, 1995, 2007; and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011.*

20 CSR 2220-7.050 License Transfer/Reciprocity

PURPOSE: This rule establishes requirements for applicants for pharmacist licensure by license transfer/reciprocity.

(1) The provisions of this rule shall be applicable to applicants for pharmacist licensure that are currently registered or licensed as a pharmacist in another United States (U.S.) state/territory who desire to be licensed by reciprocity or license transfer.

(2) Foreign Graduates. Graduates of a school/college of pharmacy not located in a U.S. state/territory shall first comply with 20 CSR 2220-7.040.

(3) Individuals seeking licensure by license transfer/reciprocity shall first file a preliminary application for license transfer with the National Association of Boards of Pharmacy (NABP). Potential applicants shall pay all NABP required fees and comply with all applicable NABP requirements.

(A) After NABP's review of the preliminary application, NABP will forward the official application for license transfer/reciprocity to the applicant which shall be completed and filed with the board along with the application fee. The official application shall be notarized and shall be accompanied by proof of fingerprinting as required by 20 CSR 2220-7.090.

(B) The NABP official application shall be submitted to the board no more than three (3) months from the issue date of the official application as designated by NABP. If the official application is not submitted to the board within the required three (3) months, the applicant shall be required to apply to NABP for reevaluation of their application and for an extension of the NABP issuance date. Applicants shall complete all reevaluation/extension requirements and pay all applicable fees required by NABP.

(4) Applicants for license transfer/reciprocity shall pass the Multistate Pharmacy Jurisprudence Examination (MPJE) for Missouri. Upon review of the official application, the board shall notify NABP if the applicant is eligible to take the MPJE. A minimum score of seventy-five (75) is required for each of the required examinations. To be eligible for examination, the applicant shall –

(A) Be currently registered or licensed as a pharmacist in another U.S. state/territory;

(B) Have been licensed as a pharmacist by examination in another U.S. state/territory;

(C) Have completed one thousand five hundred (1,500) hours of pharmacy practice experience related to the practice of pharmacy as determined by the board or shall have maintained an active pharmacist license for a period of not less than one (1) year in the state from which they are transferring that is not under disciplinary action; and

(D) Submit a copy of the applicant's Foreign Pharmacy Graduate Equivalency Committee Certification (FPGEC) certificate if the applicant is a graduate of a school/college of pharmacy not located in the United States.

(5) Test Scheduling. When an application has been completed, the board shall notify the applicant if he/she is eligible for the MPJE examination. The applicant shall schedule a testing date for the MPJE. The applicant shall satisfy all testing and scheduling requirements established by NABP and shall be responsible for completing any necessary application(s) and payment of fee(s) for scheduling/taking the examination.

(A) To avoid forfeiture of eligibility, the applicant must take the examination within six (6) months after having been determined eligible by the board for examination. If the applicant does not take the examination within six (6) months, the applicant shall be required to reapply to the board for examination/licensure and again pay the reciprocity application fee.

(B) A determination by the board that an applicant is eligible for examination does not guarantee that the applicant will be issued a Missouri pharmacist license. The board reserves the right to deny an applicant for licensure that has been approved to take the MPJE, as authorized by Missouri law.

(6) Retesting. If an applicant fails to achieve a score of seventy-five (75) on the MPJE, the candidate shall retake and pass the examination before a license can be issued. Applicants who fail to achieve a passing score shall file an application for reexamination with the board and pay the examination application fee each time. All examinations are scored independently and may be retaken independently.

(A) The board shall review and approve any applicant that fails the MPJE two (2) consecutive times prior to the applicant being declared eligible to retest. A candidate shall not be declared eligible to retest under this subsection until approved by the board. In lieu of disapproval, the board may establish a date after which the candidate shall be eligible to retest or may establish additional training or study requirements to be completed before authorization to retest is granted.

(B) Applications for reexamination shall be submitted on a form provided by the board. Fees for reexamination shall be non-refundable.

(7) Upon approval by the board and successful completion of the MPJE, the board may issue a pharmacist license to the applicant. All required fees must be paid prior to approval of a license transfer.

AUTHORITY: sections 338.020, 338.040, 338.060, and 338.070, RSMo 2000, and sections 338.035 and 338.140, RSMo Supp. 2012. Original rule filed Jan. 10, 2013, effective Aug. 30, 2013.*

**Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990; 338.040, RSMo 1939, amended 1961, 1969, 1981, 1990; 338.060, RSMo 1939, amended 1943, 1947, 1949, 1951, 1981, 1984, 1997, 1999; 338.070, RSMo 1939, amended 1947, 1953, 1961, 1969, 1981, 1985, 1997; 338.035, RSMo 1990, amended 1993, 1995, 2007; and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011.*

20 CSR 2220-7.060 Score Transfer

PURPOSE: This rule defines requirements for transferring North American Pharmacist Licensure Examination scores to Missouri.

(1) An applicant applying to take the North American Pharmacist Licensure Examination (NAPLEX) in another jurisdiction may have the score transferred to Missouri by completing the NAPLEX score transfer form supplied by the National Association of Boards of Pharmacy (NABP). To be eligible for score transfer, the applicant must have achieved a minimum passing score of seventy-five (75) on the NAPLEX. The applicant shall complete all required score transfer forms and pay any applicable fees as established by NABP.

(2) A score transfer applicant shall apply for and shall be required to comply with all applicable licensing/application requirements as otherwise established by Chapter 338, RSMo, and 20 CSR 2220-7.010 through 20 CSR 2220-7.090.

(3) A NAPLEX score transferred to Missouri shall only be deemed valid for a period of five (5) years.

AUTHORITY: sections 338.020, 338.040, and 338.070, RSMo 2000, and section 338.140, RSMo Supp. 2012. Original rule filed Jan. 10, 2013, effective Aug. 30, 2013.*

**Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990; 338.040, RSMo 1939, amended 1961, 1969, 1981, 1990; 338.070, RSMo 1939, amended 1947, 1953, 1961, 1969, 1981, 1985, 1997; and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011.*

20 CSR 2220-7.070 Temporary Pharmacist License (Post-Graduate Training)

PURPOSE: This rule establishes requirements for obtaining a temporary pharmacist license to practice pharmacy for pharmacists completing post-graduate training programs.

(1) Applicants for Post-Graduate Training. Pursuant to section 338.043, RSMo, a pharmacist licensed or registered in another state may apply for a temporary pharmacist license to complete a post-graduate pharmacy training program in the state of Missouri.

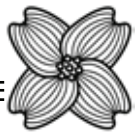
(2) Applicants for a temporary pharmacist license shall file an application on a form provided by the board with the application fee. The application will not be considered unless it is fully completed and properly attested. The application shall include:

(A) The name and signature of a Missouri-licensed pharmacist who will be supervising the applicant. The supervising pharmacist's license shall be active in Missouri and shall not be under discipline with the board;

(B) The name and address of all locations where the applicant will be practicing and a description of the applicant's proposed duties;

(C) A portrait photograph which measures two inches by two inches (2" × 2"); and

(D) A protocol which outlines the applicant's duties. At a minimum, the protocol shall define and include:



1. The type of practice to be performed and a specific job description of professional duties and functions to be completed;

2. The identity of the supervising pharmacist which includes a statement attesting to the ability and understanding of responsibilities involved;

3. A complete listing of all affiliations to be utilized during the licensure period; and

4. A complete listing of all locations where professional services will occur.

(3) A Missouri-licensed pharmacist who agrees to supervise a temporary pharmacist licensee shall conduct general supervision during his/her tenure as supervisor. General supervision is defined as supervision required to ensure the temporary pharmacist licensee is practicing in compliance with Missouri law. In addition, the supervisor must be available for consultation with the licensee whenever necessary. The supervising pharmacist and the temporary pharmacist licensee shall timely submit reports to the board as may be required through protocol or as requested by the board in assessing outcomes or adherence to board requirements.

(A) No applicant for a temporary pharmacist license shall commence practicing until the temporary pharmacist license is issued.

(B) The board may terminate a temporary pharmacist license at its own discretion if, in the opinion of the board, any of the board requirements have not been adhered to. The licensee shall be notified in writing by mail when board action results in the termination of a temporary pharmacist license.

(C) A temporary pharmacist licensee shall only be authorized to practice pharmacy at the location(s) identified in the temporary pharmacist's application for licensure. A temporary pharmacist shall notify the board if the temporary licensee changes his/her supervising pharmacist. The board shall approve a change in supervising pharmacist prior to the supervision commencing. A temporary pharmacist licensee shall not practice under the supervision of a pharmacist without approval of the board.

(D) A temporary pharmacist license issued pursuant to this rule automatically expires at the end of the applicant's Missouri-based training program identified in the application and protocol. Temporary pharmacist licensees shall not practice pharmacy in this state beyond the expiration date of their temporary license.

(4) The temporary licensing program is not intended to replace or conflict with any requirements or provisions of Missouri law or the rules of the board regarding internships or pharmacy practice experience. Students enrolled in a school/college of pharmacy seeking to rotate through a licensed pharmacy or to gain pharmacy practice experience in Missouri shall not qualify for licensure under this section but may apply for an intern license as governed by the rules of the board.

(5) If a temporary pharmacist licensee desires to acquire a permanent license or desires to practice pharmacy outside the provisions of this rule, then the temporary licensee shall be required to complete all applicable Missouri pharmacist licensure requirements. If a permanent pharmacist application is denied by the board, the temporary pharmacist license shall be considered invalid after notification is sent to the applicant/licensee by certified mail.

AUTHORITY: sections 338.020 and 338.070, RSMo 2000, and sections 338.043 and 338.140, RSMo Supp. 2012. Original rule filed Jan. 10, 2013, effective Aug. 30, 2013.*

**Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990; 338.070, RSMo 1939, amended 1947, 1953, 1961, 1969, 1981, 1985, 1997; 338.043, RSMo 1990, amended 1997, 2001; and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011.*

20 CSR 2220-7.075 Temporary Pharmacist License for Non-Resident Military Spouses

PURPOSE: This rule establishes requirements for obtaining a temporary pharmacist license for non-resident military spouses as authorized by section 324.008, RSMo.

(1) A non-resident spouse of an active duty member of the Armed Forces of the United States who has been transferred or is scheduled to be transferred to the state of Missouri, is domiciled in the state of Missouri, or who has moved to the state of Missouri on a permanent change-of-station basis, may apply for a temporary Missouri pharmacist license to practice in this state. To be eligible for a temporary pharmacist license under this rule, the nonresident military spouse must meet the requirements of section 324.008, RSMo. No application fee shall apply.

(2) Applicants for a temporary pharmacist license must file an application on a form provided by the board that includes:

(A) The applicant's name and address;

(B) The name and address of all locations where the applicant will be practicing, if known;

(C) A portrait photograph which measures two inches by two inches (2" × 2");

(D) Official verification from a state or territory of the United States showing that the applicant holds a current and active pharmacist license in the applicable state or territory;

(E) Evidence that the applicant meets the practice requirements of section 324.008.3, RSMo; and

(F) An attestation that the temporary pharmacist agrees to comply with all state and federal laws applicable to the practice of pharmacy, including, but not limited to, Chapter 338, RSMo, the rules of the board and all controlled substance laws.

(3) A temporary license under this section shall be valid for one-hundred eighty (180) days but may be extended for an additional one-hundred and eighty (180) days for good cause at the discretion of the board. Temporary pharmacist licensees cannot practice pharmacy in Missouri beyond the expiration date of their temporary license.

(4) A temporary pharmacist must complete all applicable Missouri pharmacist licensure requirements to acquire a permanent Missouri pharmacist license. If a permanent pharmacist application is denied by the board, the temporary pharmacist license shall be considered invalid after notification is sent to the applicant/licensee by certified mail.

AUTHORITY: sections 324.008 and 338.043, RSMo 2016, and section 338.140, RSMo Supp. 2019. Original rule filed Nov. 6, 2019, effective May 30, 2020.*

**Original authority: 324.008, RSMo 2011; 338.043, RSMo 1990, amended 1997, 2001; and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019.*

20 CSR 2220-7.080 Pharmacist License Renewal and Continuing Pharmacy Education

PURPOSE: This rule establishes renewal and continuing education requirements for relicensure of pharmacists in Missouri.

(1) All pharmacist licensees shall apply to renew their Missouri pharmacist license on or before October 31 of every even-numbered year. Applicants shall file a renewal application on a form provided by the board and pay the renewal fee. The renewal application must be completed correctly and in its entirety in order for it to be processed and the license renewed. Any portion of the application that is incomplete or inaccurate shall result in the rejection of the renewal application and require its return to the applicant for correction.

(A) No active pharmacist license will be renewed by the board unless the applicant has fulfilled the continuing education requirements as set forth in section 338.060, RSMo, and the provisions of this rule. At the time of renewal, a licensee shall truthfully attest he/she has completed the continuing education requirements required by this rule. The attestation shall be submitted with the renewal application and shall truthfully affirm that the licensee has completed all continuing education requirements and that proof of continuing education completion has been maintained by the pharmacist as required by section (2) of this rule. The required continuing education must be completed by the date the renewal is signed or submitted to the board.

(B) A Missouri pharmacist license that has not been renewed by the board on or before October 31 of each even-numbered year shall be deemed expired. Upon expiration, the holder of an expired license shall be deemed no longer licensed and shall not practice pharmacy in the state of Missouri until the license has been renewed by the board. To renew an expired license, the holder shall file a renewal application with the board and shall pay all delinquent fees. A delinquent fee shall not be required if the renewal application was postmarked or submitted via the board's electronic renewal system on or before October 31 of each even-numbered year. Renewal applications received prior to October 31 that are returned to the applicant for correction will not be considered late and subject to the delinquent fee if the corrected application is returned to the board within thirty (30) days after receipt.

(C) Any person who fails to renew his/her pharmacist license within two (2) years of its expiration shall be treated in the same manner as a person who has never been licensed and shall be required to file a new pharmacist license application with the board.

(2) Required Hours. As a condition of renewal, all active Missouri pharmacist licensees shall complete thirty (30) hours of continuing education during the two (2) year continuing education reporting period preceding renewal of the license. For purposes of this rule, the reporting period is the twenty-four- (24-) month period beginning on November 1 of even-numbered years and ending on October 31 of even-numbered years. Continuing education hours earned after October 31 of even-numbered years shall apply to the next continuing education period.

(A) A pharmacist first licensed by the board within twelve (12) months immediately preceding the October 31 biennial renewal date shall be exempt from the continuing pharmacy education requirements for that reporting period.

(B) Hours obtained in excess of the thirty (30) hours required by this rule may not be carried forward to satisfy the requirements for the next reporting period.

(3) Continuing Education Course Approval.

(A) Except as otherwise provided herein, continuing education shall only be granted for a post-graduate course that is related to the practice of pharmacy and that is –

1. Approved by the Accreditation Council for Pharmaceutical Education (ACPE) for continuing education;

2. Offered by a state, federal, or local governmental or regulatory agency and approved by the board; or

3. Related to the practice of pharmacy, as approved by the board.

(B) Continuing education courses may include institutes, seminars, lectures, conferences, workshops, extension study, correspondence courses, teaching, professional meetings, self-study courses, and any other methods approved by the board. The courses must be pharmacy related and shall comply with the other continuing education requirements of this rule.

(C) Continuing pharmacy education programs approved by ACPE shall be accepted as approved continuing education courses for purposes of license renewal and are not required to be individually submitted to the board for prior approval.

(D) The board shall not grant continuing education credit for any course that is taken before it is approved by the board or ACPE.

(E) One (1) continuing education contact unit (CEU) will be the equivalent of ten (10) clock hours of participation in programs approved by the board.

(4) Non-ACPE Approved Programs. Programs that are not ACPE approved must be approved by the board prior to being taken as a continuing education course. To be eligible for approval, a program shall provide for evaluation methods or examinations to assure satisfactory completion by participants. Addition-ally, the person(s) who is to instruct or who is responsible for the delivery or content of the program shall be qualified in the subject matter by education or experience.

(A) Continuing education approval requests shall be submitted to the board on forms provided by the board. The applicant shall provide detailed information relating to administration and organization of the course, teaching staff, educational content and development, methods of delivery, facilities, and evaluation.

(B) Continuing education program approval applications should be submitted at least thirty (30) days prior to the date of the proposed continuing education program, to ensure the program is approved for continuing education credit prior to the course being taken. Applications received less than thirty (30) days prior to the date of the program cannot be guaranteed to be approved prior to the date of the program. No application for approval of continuing education programs will be accepted if received less than ten (10) business days from the date such program is to be offered for continuing education purposes.

(C) Applications returned due to errors or for purposes of requesting more information shall not be considered to be received by the board until the requested corrections and/or information are made and received by the board.

(D) The executive director shall review applications for continuing education programs and may approve or deny such requests. Applicants shall be notified after a decision to approve or deny a program has been made.

(5) Credit for Educational Training.

(A) Any pharmacist who leads, instructs, or lectures to groups

of nurses, physicians, pharmacists, or others on pharmacy-related topics in organized continuing education or in-service programs shall be granted continuing education credit for the time expended during actual presentation upon adequate documentation to the board. However, a pharmacist whose responsibility is the education of health professionals shall only be granted continuing education credit for time expended in leading, instructing, or lecturing to groups of physicians, pharmacists, nurses, or others on board-approved pharmacy-related topics in an organized continuing education or in-service program outside of his/her formal responsibilities.

(B) Approval shall be requested using the procedures in section (4) of this rule. Credit for the same presentation or program will only be granted once during a renewal period.

(6) Graduate Studies. Continuing education credit will be given for undergraduate or graduate studies taken as a post-graduate in any regionally accredited pharmacy, medical, or dental educational institution of higher learning. To be eligible for credit, the studies must be related to the practice of pharmacy. Credit for undergraduate/graduate studies authorized by this rule shall be assessed as follows:

(A) 3 hours college credit	=	15 CE hours
(B) 2 hours college credit	=	10 CE hours
(C) 1 hour college credit	=	5 CE hours

(7) Licensees may obtain four (4) hours (0.4 CEU) of continuing education by attending a complete open session of a board meeting at which disciplinary hearings are scheduled, subject to the following:

(A) The licensee must sign in with the executive director or designee of the board before the meeting day begins;

(B) Licensees cannot receive continuing education credit for attendance at a board meeting if required to appear before the board;

(C) The licensee must remain in continuous attendance during the open session meeting, provided attendance shall not be required for more than eight (8) hours of an open session meeting. Except as otherwise provided in this section, partial credit will not be given if the licensee is not in attendance for the entire open session meeting;

(D) The maximum continuing education hours allowable for board meeting attendance pursuant to this subsection shall be limited to eight (8) credit hours (0.8 CEU) per biennial pharmacist renewal period.

(8) No information or advertisements shall contain information that a continuing education program has been approved by the board unless the program is accredited by ACPE or notification has been received from the board that the program has been approved.

(9) Inactive Licenses. In lieu of submitting proof of continuing education, a pharmacist may apply for an inactive license at the time of license renewal. To be deemed inactive, the pharmacist shall file a renewal application with the board with the applicable fee and request inactive status on the renewal application. An inactive license shall then be issued and may be renewed at subsequent renewal periods. While the inactive license is in effect, the pharmacist shall not practice pharmacy.

(A) The renewal fee will be the same for active and inactive licenses.

(B) Before an inactive license can be returned to active status, the licensee shall submit proper evidence that he/she has obtained at least fifteen (15) continuing education hours for each year that his/her license was inactive. The licensee may obtain the required continuing education hours during any time period while the license is on inactive status, as long as the hours are obtained prior to applying for return to active status.

(10) Any licensee who has an expired pharmacist license and seeks to renew the license pursuant to section 338.060.2, RSMo, shall present proper evidence that he/she has obtained the required number of continuing education hours during the period that his/her license was expired.

(11) A pharmacist shall maintain proof of completion of continuing education credits for a minimum of four (4) years after the continuing education has been completed. Licensees shall maintain a completed certification from ACPE or the approved continuing education provider indicating the course name and date of the program, the name of the participant, the date credit was earned, and, if applicable, the ACPE course number.

(12) The board may audit a licensee to assess the authenticity and validity of continuing education hours submitted for relicensure. Failure to provide proof of completion of the required continuing education credits when requested to do so by the board shall be considered a violation.

(A) In accordance with section 338.060, RSMo, any licensee that has not completed and retained the required evidence of all required continuing education shall complete any outstanding continuing education and pay a delinquent fee as provided by this rule and may be subject to disciplinary action pursuant to section 338.055, RSMo. The board may also audit past renewal periods and/or require that proof of continuing education credits be submitted with the licensee's renewal application.

(B) The following continuing education delinquent fees are applicable:

1. Less than one (1) hour missing one hundred dollars ($100);
2. Two (2) to ten (10) hours missing five hundred dollars ($ 500);
3. Eleven (11) to fifteen (15) hours missing seven hundred fifty dollars ($750); or
4. Sixteen (16) or more hours missing one thousand dollars ($1,000).

AUTHORITY: sections 338.020, 338.060, and 338.070, RSMo 2016, and section 338.140, RSMo Supp. 2019. Original rule filed Jan. 10, 2013, effective Aug. 30, 2013. Amended: Filed May 6, 2019, effective Nov. 30, 2019. ***

**Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990, 2014; 338.060, RSMo 1939, amended 1943, 1947, 1949, 1951, 1981, 1984, 1997, 1999; 338.070, RSMo 1939, amended 1947, 1953, 1961, 1969, 1981, 1985, 1997; and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011, 2019.*

***Pursuant to Executive Order 21-07, 20 CSR 2220-7.080, section (2) was suspended from July 13, 2020 through August 5, 2021.*

20 CSR 2220-7.090 Fingerprint Requirements

PURPOSE: This rule establishes guidelines for the submission of fingerprints by applicants.

(1) Applicants for licensure or registration required to provide fingerprints to the board shall include:

(A) All pharmacist applicants, including, applicants by examination, score transfer, reciprocity/transfer, and foreign graduates;

(B) Drug distributor license manager-in-charge (unless currently licensed as a pharmacist in the state of Missouri);

(C) Pharmacy technician applicants;

(D) Owners with a ten percent (10%) or more interest in a drug distributor applicant (non-publicly held companies only); and

(E) Intern pharmacist applicants.

(2) An applicant required to submit fingerprints pursuant to this rule shall submit fingerprints for the purpose of conducting a criminal background check by the Missouri State Highway Patrol (MSHP) and Federal Bureau of Investigation (FBI). The applicant shall provide proof of submission of fingerprints to MSHP's approved vendor(s) for both a MSHP and FBI criminal history background check. Proof shall consist of any documentation acceptable to the board. Any fees due for a fingerprint background check shall be paid by the applicant directly to the MSHP or its approved vendor(s).

(3) Information collected under this criminal history review will be held as confidential in accordance with state and federal laws governing the dissemination of criminal history information.

(4) The board may require an applicant to be fingerprinted again and pay any required fingerprinting fees, if the application process is not completed within six (6) months of the board's receipt of the application.

(5) The board may, in the course of an investigation of a licensee, require that fingerprints be submitted for a criminal history background check as provided for in this rule.

AUTHORITY: sections 338.020, 338.040, 338.070, and 338.280, RSMo 2000, and sections 338.035 and 338.140, RSMo Supp. 2012. Original rule filed Jan. 10, 2013, effective Aug. 30, 2013.*

**Original authority: 338.020, RSMo 1939, amended 1947, 1949, 1981, 1990; 338.040, RSMo 1939, amended 1961, 1969, 1981, 1990; 338.070, RSMo 1939, amended 1947, 1953, 1961, 1969, 1981, 1985, 1997; 338.280, RSMo 1951, amended 1971, 1981; 338.035, RSMo 1990, amended 1993, 1995, 2007; and 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011.*

20 CSR 2220-8

Title 20—DEPARTMENT OF COMMERCE AND INSURANCE
Division 2220—State Board of Pharmacy
Chapter 8—Third-Party Logistic Providers and Drug Outsourcer Facilities

20 CSR 2220-8.010 Definitions

PURPOSE: This rule adopts definitions for purposes of 20 CSR Chapter 8 governing drug outsourcers and third-party logistics providers.

(1) Definitions. The following definitions are applicable to 20 CSR 2220 Chapter 8:

(A) "Drug outsourcer" or "Drug outsourcer facility"—An entity registered with the United States Food and Drug Administration pursuant to section 503(B) of the federal Food, Drug and Cosmetic Act, as amended by the Drug Quality and Security Act (21 section USC 353b);

(B) "Drug related device"—An article that is not considered a prescription drug under federal law, but which meets the definition of a device as provided in 21 U.S.C. 321(h) and 21 U.S.C. 360j(e);

(C) "Drug" or "Prescription drug"—A legend drug as defined by section 338.330, RSMo; and

(D) "Third-party logistics provider" or "3PL"—An entity that provides or coordinates warehousing, or other logistics services of a prescription drug or drug-related device on behalf of a manufacturer, wholesale distributor, or dispenser of such a product, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product. A third-party logistics provider license is required for entities conducting 3PL activities that are physically located in this state or shipping drug products into Missouri.

AUTHORITY: sections 338.140, 338.150, 338.280, and 338.350, RSMo 2016, and sections 338.315, 338.330, 338.333, 338.337, and 338.340, RSMo Supp. 2018. Emergency rule filed Nov. 28, 2018, effective Dec. 8, 2018, expired June 5, 2019. Original rule filed Nov. 28, 2018, effective May 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011, 2013; 338.280, RSMo 1951, amended 1971, 1981; 338.315, RSMo 1989, amended 2011, 2012, 2014, 2018; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; 338.333, RSMo 1989, amended 2010, 2012, 2018; 338.337, RSMo 1989, amended 2009, 2010, 2018; 338.340, RSMo 1989, amended 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-8.020 Licensing Requirements

PURPOSE: This rule establishes licensing requirements and procedures for drug outsourcers and third-party logistics providers.

(1) No person or entity may act as a third-party logistics provider (3PL) or a drug outsourcer unless the person/entity has obtained the applicable 3PL or drug outsourcer license from the board. A separate license is required for each facility owned or operated as a 3PL or drug outsourcer.

(A) Applicants must submit a completed application to the board with the applicable fee along with the following information:

1. The name, full business address, e-mail address, and telephone number of the applicant and the facility where third-party logistics provider services or drug outsourcer activities will be provided, if different;

2. All trade or business names used by the licensee;

3. For 3PL applicants, the name, address, telephone number, and e-mail address of a manager-in-charge that meets the requirements of 20 CSR 2220-8.030 along with his/her employment history for the previous seven (7) years and a notarized manager-in-charge affidavit;

4. For drug outsourcer applicants, the name, address, telephone number, and e-mail address of a pharmacist responsible for supervising the facility who holds a current and active pharmacist license issued by a U.S. state or territory. If the designated pharmacist does not have a current and active Missouri pharmacist license, official verification must be submitted from the board of pharmacy or equivalent pharmacist governmental licensing agency verifying that the designated pharmacist holds a current and active pharmacist license issued by such state/territory;

5. The type of ownership or legal structure; and

6. The name(s) of the owner, operator, or both, of the licensed entity, including:

A. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity. The sole proprietor must sign the application;

B. If a partnership or limited liability partnerships, the name of each partner and the name of the partnership. A partner or general partner must sign the application; or

C. If a corporation, the name of the corporate president, vice president, secretary, treasurer, chief executive officer, board of directors, and senior vice presidents, or their equivalents, the corporate name(s), and the name of the state of incorporation. An officer of the corporation must sign the application.

(B) A license will not be issued to a facility located in Missouri until the board or its duly authorized agent has inspected the premises of the new location and approved it. For non-resident applicants, an inspection report must be submitted as required by 20 CSR 2220-8.030.

(C) All third-party logistics provider and drug outsourcer licenses will expire on the date specified by the director of the Division of Professional Registration by appropriate rule. Once issued, licenses must be conspicuously posted in the licensed facility where 3PL or drug outsourcer operations are conducted.

(D) A 3PL or drug outsourcer license will not be issued to any location where drugs are stored or maintained that is in a residence or that shares an address and/or physical space with a business not related to distributing prescription drugs or drug-related devices, or not licensed and regulated by the state of Missouri.

(E) An application will become null and void if the applicant fails to complete the process for licensure within six (6) months after the application is received by the board.

(F) All application fees are non-refundable.

(2) Change of Ownership. A third-party logistics provider or drug outsourcer license shall become void on the effective date of any change of ownership. The subsequent owners must obtain a new license from the board prior to operating as a third-party logistics provider or drug outsourcer in this state, provided a temporary license may be issued to the new ownership until a new license is granted as outlined in section (5). Facilities located in Missouri must be inspected by the board prior to issuing a new license.

(A) A change of ownership of a sole proprietorship is deemed to have occurred when—

1. The business is sold and the sale becomes final;

2. The proprietor enters into a partnership with another individual or business entity; or

3. The proprietor dies, provided, the proprietor's estate may continue to operate the third-party logistics provider or drug outsourcer facility for a period of no more than one (1) year if all appropriate fees are paid.

(B) If a corporation owns a third-party logistics provider or drug outsourcer, a new license is not required if the owners of the stock change. If a limited liability partnership or a limited liability company owns a third-party logistics provider or drug outsourcer, a

new license is not required if the partners or members of the company change, as long as the partnership or company is not dissolved by the change. Written notice must be filed with the board within thirty (30) days after a change of twenty-five percent (25%) or more in the ownership of corporation stock, or the partners of a limited liability partnership, or the members of a limited liability company. The required notification must be in writing and notarized.

(C) When a sole proprietorship, corporation, limited liability partnership, or limited liability company begins or ceases ownership of a third-party logistics provider or drug outsourcer, a new license must be obtained regardless of the relationship between the previous and subsequent owners.

(3) Change of Location. A third-party logistics provider or drug outsourcer license is only valid for the address listed on the license issued by the board. If the location of a third-party logistics provider or drug outsourcer facility changes either within the existing facility or to a new facility, a change of location application must be submitted to the board with the applicable fee. A Missouri located facility may not open for business at the new location until the board or its duly authorized agent has inspected the premises of the new location and approved it. Once approved, the board will issue a license for the new location with the same license number as the previous license. A license will remain valid if the facility address changes but not the location, in such case an amended license will be issued on request without charge.

(4) Change of Name. Licensees may only conduct 3PL or drug outsourcing activities in the state of Missouri under the name(s) licensed by the board. If a name change occurs, a change of name application must be submitted to the board with the applicable fee within three (3) business days of the change. The facility's license will be reissued under the new name with the same license number. A change of ownership application is required if the licensee is changing corporate or legal structure or otherwise changing ownership.

(5) Temporary Licenses. The board may grant a temporary license to an applicant, subject to any terms or conditions the board deems necessary or appropriate, to allow the business to continue operating in Missouri until the board makes a determination on the applicant's license application. Unless otherwise authorized by the board, temporary licenses are valid for one (1) year or until final action by the board, whichever is less.

(A) The board will consider the following in determining whether to issue a temporary license:

1. Any conduct or activity that constitutes grounds for denial or discipline under section 338.055, RSMo;

2. The applicant's compliance with state and federal drug and/or distribution laws;

3. Any failure to produce records or information requested by the board or failure to provide full and truthful information;

4. Failure to cooperate with any board request or inquiry related to the application;

5. Current or pending disciplinary action by any federal, state, or local government against any license or registration currently or previously held by the applicant;

6. Compliance with licensing requirements under previously granted licenses, if any; and

7. Any other factor relevant to the applicant's ability to safely or properly operate in Missouri.

(B) A notification letter will be sent to the applicant once a decision is made on the applicant's permanent license. The temporary license will be considered void ten (10) days after board notification is sent to the applicant.

(C) Applicants issued a temporary license may conduct business in this state as a third-party logistics provider or, for drug outsourcer applicants, as a drug outsourcer as long as all state and federal laws governing provider/drug outsourcing activities are followed and no action that results in professional misconduct as outlined in section 338.055, RSMo, occurs.

(6) A nonresident third-party logistics provider or drug outsourcer licensed by the board must designate a registered agent in Missouri for service of process. Any licensee that does not designate a registered agent shall be deemed to have designated the Missouri secretary of state to be its true and lawful attorney for service of process in any action or proceeding against the third-party logistics provider or drug outsourcer growing out of or arising from such 3PL or drug outsourcing services. Service of process shall be accomplished as authorized by law.

(7) Licensure Exemptions. A Missouri 3PL or drug outsourcer license is not required for the following activities—

(A) The sale, purchase, transfer, or trade of a drug or an offer to sell, purchase, transfer, or trade a drug for emergency administration to an individual patient if a delay in therapy would negatively affect a patient outcome. Prior to the distribution, the unlicensed entity or proposed recipient must file a written request with the board to approve the emergency transaction. The amount sold, purchased, transferred, or traded shall not exceed one percent (1%) of the 3PL's or drug outsourcer's total gross prescription sales or, if prescriptions are not sold, one percent (1%) of the 3PL's/drug outsourcer's total drug purchases;

(B) The storage or distribution of drugs by a local, state, or federal facility that are received from the Strategic National Stockpile or the state stockpile for the purpose of providing those drugs in an emergency situation as authorized by a state or federal agency; and

(C) The sale, purchase, transfer, or trade of a prescription drug by a 3PL to alleviate a temporary shortage of a prescription drug that is in limited supply or unavailable due to delays in or interruption of supply. Drugs sold, purchased, transferred, or traded pursuant to this section shall only be sold, purchased, transferred, or traded directly from an importer or manufacturer authorized by or registered with the United States Food and Drug Administration (FDA) to import or manufacture the drug that is unavailable or in short supply. In addition, sales, purchases, transfers, or trades shall be limited to the period of shortage and to the drug that is unavailable or in limited supply. Documentation of FDA authorization or registration shall be maintained in the 3PL's records.

AUTHORITY: sections 338.140, 338.150, 338.280, and 338.350, RSMo 2016, and sections 338.315, 338.330, 338.333, 338.337, and 338.340, RSMo Supp. 2018. Emergency rule filed Nov. 28, 2018, effective Dec. 8, 2018, expired June 5, 2019. Original rule filed Nov. 28, 2018, effective May 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011, 2013; 338.280, RSMo 1951, amended 1971, 1981; 338.315, RSMo 1989, amended 2011, 2012, 2014, 2018; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; 338.333, RSMo 1989, amended 2010, 2012, 2018; 338.337, RSMo 1989, amended 2009, 2010, 2018; 338.340, RSMo 1989, amended 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-8.030 Nonresident Third-Party Logistics Providers/Drug Outsourcer Facilities

PURPOSE: This rule establishes additional guidelines for non-resident third-party logistics providers and drug outsourcer applicants.

(1) Nonresident third-party logistics (3PL)

providers or drug outsourcer facilities may not act as a third-party logistics provider or a drug outsourcer or ship, mail, or deliver legend drugs, or for drug outsourcers, compounded drugs into Missouri without first obtaining the applicable license from the board. Nonresident third-party logistics providers or drug outsourcers may be licensed by reciprocity if they—

(A) Possess a valid 3PL or drug outsourcer license or an equivalent license that is in good standing in the state or foreign jurisdiction in which they are located that was issued pursuant to legal standards comparable to those which must be met by a Missouri third-party logistics provider or drug outsourcer; and

(B) Are located in a state or foreign jurisdiction which extends reciprocal treatment to a third-party logistics provider of this state or, for drug outsourcer applicants, a drug outsourcer of this state.

(2) Except as otherwise provided in this rule, applicants for a nonresident third-party logistics provider or drug outsourcer license must comply with 20 CSR 2220-8.020, including, but not limited to, all application, change of ownership, change of location, and change of name requirements. In addition to the requirements of 20 CSR 2220-8.020, nonresident applicants must also submit the following with their application:

(A) A copy of the applicant's 3PL or drug outsourcer license or its equivalent from the state or foreign jurisdiction where the nonresident third-party logistics provider or drug outsourcer facility is located;

(B) An official verification from the state or foreign jurisdiction where the third-party logistics provider or drug outsourcer facility is located verifying that the applicant holds a current and active third-party logistics provider license or its equivalent, for drug outsourcer applicants, a drug outsourcer license or its equivalent issued by such state or foreign jurisdiction;

(C) A copy of the applicant's most recent inspection report or findings from the applicant's resident board of pharmacy or its equivalent state/foreign regulatory body. For 3PL applicants, the inspection must have occurred within the last twenty-four (24) months. For drug outsourcer applicants, the inspection must have occurred within the last eighteen (18) months. If a state inspection is unavailable, an inspection by the Missouri Board of Pharmacy, the United States Food and Drug Administration (FDA) or the National Association of State Boards of Pharmacy must be submitted or a similar inspection by an entity approved by the board;

(D) If controlled substances will be shipped into Missouri, a copy of the applicant's federal controlled substance registration and, if applicable, a copy of the applicant's state controlled substance registration from the state where the applicant is located; and

(E) If requested by the board, any inspection reports, correction active responses, warning notices, deficiency notices, or any other related state, federal, or foreign jurisdiction report or notice related to the applicant's handling, distribution, manufacturing, or sale of medication.

AUTHORITY: sections 338.140, 338.150, 338.280, and 338.350, RSMo 2016, and sections 338.315, 338.330, 338.333, 338.337, and 338.340, RSMo Supp. 2018. Emergency rule filed Nov. 28, 2018, effective Dec. 8, 2018, expired June 5, 2019. Original rule filed Nov. 28, 2018, effective May 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011, 2013; 338.280, RSMo 1951, amended 1971, 1981; 338.315, RSMo 1989, amended 2011, 2012, 2014, 2018; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; 338.333, RSMo 1989, amended 2010, 2012, 2018; 338.337, RSMo 1989, amended 2009, 2010, 2018; 338.340, RSMo 1989, amended 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-8.040 Standards of Operation (Drug Outsourcers)

PURPOSE: This rule provides standards of operation for drug outsourcers licensed by the board.

(1) Drug outsourcers shall comply with all applicable state and federal laws governing drug outsourcing activities, including, but not limited to, controlled substance laws and the federal Food, Drug and Cosmetics Act, as amended by the Drug Quality and Security Act.

(A) Except as otherwise required by federal law, drug outsourcers must comply with all applicable current good manufacturing practices (cGMPs) required by federal law and the United States Food and Drug Administration.

(B) A separate Missouri drug distributor license is required if a drug outsourcer is engaged in any additional drug distribution activities as defined by Chapter 338, RSMo, other than drug outsourcing. A pharmacy license is required if medication will be dispensed pursuant to a patient-specific prescription.

(2) No drug outsourcer license will be issued unless the facility is under the direct supervision of a licensed pharmacist who has been designated with the board and who will be responsible for facility operations and ensuring compliance with state and federal law. For drug outsourcers located in Missouri, the pharmacist must hold a current and active Missouri pharmacist license. For non-resident drug outsourcers, the pharmacist must hold a current and active pharmacist license issued by Missouri or another U.S. state/territory.

(A) Drug outsourcing activities must be conducted at all times under the supervision of the designated pharmacist. The pharmacist must be actively involved in and aware of the daily operations of the outsourcing facility and must ensure that policies and procedures governing drug outsourcing operations are current and accurate.

(B) In the event the pharmacist designated with the board to supervise the facility changes, the drug outsourcer may not continue operations until a new pharmacist is named to supervise the facility. A change of pharmacist application must be submitted to the board with the applicable fee within fifteen (15) calendar days after a new pharmacist is designated to supervise.

(3) Sterile compounding and drug outsourcing activities must be safely and accurately performed at all times to ensure that only drugs of appropriate quality are distributed. No counterfeit, misbranded, expired, or adulterated drug may be compounded, distributed, sold, or brokered by or on behalf of a drug outsourcer.

(A) All individuals employed or engaged in sterile compounding or drug outsourcer activities must have sufficient education, training, or experience to perform the duties assigned. A list must be maintained of all individuals engaged in sterile compounding or in drug outsourcer activities with a description of the individual's duties.

(B) Drug outsourcers located in this state may only purchase or receive legend drugs and/or drug related devices from an entity licensed as a Missouri drug distributor, third-party logistics provider, drug outsourcer, or pharmacy.

(C) Medication held for distribution must be stored in a secure area where only authorized personnel have access to them. A list of all individuals who have independent access to drug storage areas must be maintained. The list must be maintained for three (3) years and must be readily retrievable on request of the board or the board's authorized designee.

(D) The outside shipping container of received medication and product ingredients must be visually examined for identity and for container and content integrity to prevent

the acceptance or distribution of any contaminated, adulterated, or otherwise unfit medication. Any prescription drug or drug ingredient whose immediate or sealed outer container or sealed secondary container has been opened, used, or improperly compromised must be quarantined and physically separated from the facility's active inventory.

(E) Medication shipped for distribution or further use must be carefully inspected prior to shipping/distribution for identity and to ensure no contaminated, adulterated, or misbranded drug or compounded preparation is distributed. Licensees shall maintain and follow security procedures for delivering drugs and compounded preparations from the facility to the destination site.

(F) Drug outsourcers must develop and implement written policies and procedures to ensure the safe and appropriate delivery of prescription drugs within the temperature requirements recommended by the manufacturer or the *United States Pharmacopeia* (USP).

(G) For returned medication, licensees must consider the conditions under which the drug has been held, stored, or shipped, the condition of the drug and its container/carton, and any other relevant factor that may reflect on the drug's fitness for further use or distribution. If the conditions under which medication has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity.

(H) Drug products must be labeled as required by the manufacturer and state and federal law, including, section 338.059.2, RSMo.

(4) Facility Standards. The following standards are applicable to all drug outsourcing facilities:

(A) Drug outsourcing facilities must be securely maintained at all times to prevent unauthorized access to the facility, drugs, or drug storage areas. Additionally, the facility must be equipped with a security system that will provide suitable protection against theft and diversion, including, electronic theft or diversion. All facilities must be equipped with an alarm system to detect unauthorized entry after hours.

(B) Appropriate sewage disposal and a hot and cold water supply must be available.

(C) Waste and hazardous materials must be handled and disposed of in compliance with applicable state and federal law.

(D) Drug outsourcing facilities must be free from insects, vermin, and animals of any kind, except for service animals as defined by the Americans with Disabilities Act (ADA).

(E) Medication must be properly stored and maintained in a thermostatically controlled area within temperature and humidity requirements as provided in the FDA approved drug product labeling or the *United States Pharmacopeia* (USP).

(F) Temperatures in drug storage areas must be recorded and reviewed at least once each day the facility is in operation. Alternatively, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings that alerts the pharmacist designated with the board for supervising the facility or alerts designated facility staff when temperatures are outside of the required range.

(G) No outdated, misbranded, or adulterated drugs or devices may be dispensed or maintained within the facility's active inventory, including prescription and related nonprescription items. Outdated, misbranded, or adulterated medication must be quarantined in a clearly identified segregated area and maintained separately from drugs intended for distribution or compounding.

(H) Medication may not be stored on the floor. Drug products must be raised above floor level and placed on a pallet or similar device.

(I) Drug outsourcers must report any recall of medication or a sterile preparation that is, or suspected to be, misbranded, adulterated, or non-sterile. Recalls must be reported to the board in writing within seven (7) days of a recall.

(5) Policies and Procedures. Drug outsourcers must maintain and follow current and accurate policies and procedures governing all aspects of the facility's drug outsourcing activities. Policies and procedures may be physically or electronically maintained at the facility, provided the policies/procedures are immediately retrievable at the request of the board or the board's authorized designee.

(6) Record-Keeping. Drug outsourcer records must be accurately maintained in compliance with state and federal law. Additionally, licensees must maintain inventories and records of all transactions regarding the receipt, distribution, compounding, or other disposition of prescription drugs or sterile preparations. Unless otherwise provided by law, records required by Chapter 338 or this rule must be maintained for three (3) years. Records may be manually or electronically maintained, provided the record is readily retrievable and available for inspection, photographing, or duplication at the request of the board or the board authorized designee, or at the request of authorized federal, state, or local law enforcement officials. Records maintained offsite and not electronically retrievable at the drug outsourcer facility must be made available for inspection within two (2) working days of a request by the board or an authorized board designee.

AUTHORITY: sections 338.140, 338.150, 338.280, and 338.350, RSMo 2016, and sections 338.315, 338.330, 338.333, 338.337, and 338.340, RSMo Supp. 2018. Emergency rule filed Nov. 28, 2018, effective Dec. 8, 2018, expired June 5, 2019. Original rule filed Nov. 28, 2018, effective June 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011, 2013; 338.280, RSMo 1951, amended 1971, 1981; 338.315, RSMo 1989, amended 2011, 2012, 2014, 2018; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; 338.333, RSMo 1989, amended 2010, 2012, 2018; 338.337, RSMo 1989, amended 2009, 2010, 2018; 338.340, RSMo 1989, amended 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-8.045 Standards of Operation (Third-Party Logistics Providers)

PURPOSE: This rule provides standards of operation for third-party logistic providers licensed by the board.

(1) Third-party logistics providers (3PL) shall comply with all applicable state and federal law governing 3PL activities, controlled substances and drug distribution/handling, including, but not limited to, the federal Food, Drug and Cosmetics Act, as amended by the federal Drug Supply Chain Security Act (20 USC section 351 et seq).

(2) Manager-In-Charge. No third-party logistics provider license will be issued unless the facility is under the direct supervision of a manager-in-charge who has been designated with the board and who will be responsible for facility operations and ensuring compliance with state and federal law. The designated manager-in-charge must have appropriate education or experience to perform the duties assigned. At a minimum, the manager-in-charge must have at least two (2) years of education/experience in third-party logistics provider or drug distribution standards of operation or legal/compliance requirements. Education beyond a high school diploma or its equivalent may be used to meet these minimum requirements.

(A) 3PL activities must be conducted

under the supervision of the designated manager-in-charge. The manager-in-charge must be actively involved and aware of the daily operations of the third-party logistics provider and must be physically present at the third-party logistics provider facility during normal business hours, except for absences due to illness, scheduled vacations, or other authorized absence. The manager-in-charge must ensure that policies and procedures governing the third-party logistics provider's operations are current and accurate.

(B) In the event the manager-in-charge designated with the board changes, the third-party logistics provider may not continue operations until a new manager-in-charge is named. A change of manager-in-charge application must be submitted to the board with the applicable fee within fifteen (15) calendar days after the new manager-in-charge is designated.

(C) In addition to the manager-in-charge, all individuals employed or engaged in third-party logistics operations must have sufficient education, training, or experience to perform the duties assigned. A list must be maintained of all managers or other individuals in charge of 3PL activities or drug distribution, storage and handling, and a description of the individual's duties.

(3) Facility Standards. The following requirements are applicable to all 3PL facilities:

(A) All state and federal 3PL, controlled substance and drug distribution licenses or registrations must be current and accurate. The facility's Missouri 3PL license must be conspicuously posted at the 3PL facility licensed by the board;

(B) 3PL facilities must be of suitable size and construction to allow proper cleaning, maintenance, and facility operations. Appropriate sewage disposal and a hot and cold water supply must be available. The outside perimeter of the premises must be well-lit; and

(C) 3PL facilities must be securely maintained at all times to prevent unauthorized access to the facility, drugs, or drug storage areas. Additionally, 3PL facilities must be equipped with a security system that will provide suitable protection against theft and diversion, including, electronic theft or diversion. All facilities must be equipped with an alarm system to detect entry after hours.

(4) Drug Storage and Distribution. 3PL activities must be safely and accurately performed at all times in compliance with applicable state and federal law. Only drugs of appropriate quality may be distributed. No counterfeit, outdated, misbranded, expired, or adulterated drug may be distributed, sold, or brokered by or on behalf of a 3PL.

(A) Appropriate lighting, sanitation, ventilation, and humidity must be maintained in all areas where drugs are stored or distributed. Aisles, walkways, and shelves in drug storage areas must be clear of debris, dirt, and filth. Dust must be kept at low levels through adequate ventilation or proper cleaning procedures.

(B) Waste and hazardous materials must be handled and disposed of in compliance with applicable state and federal law.

(C) Drug storage areas must be free from insects, vermin, and animals of any kind, except for service animals as defined by the Americans with Disabilities Act (ADA).

(D) Drugs must be properly stored and maintained in a thermostatically controlled area within temperature and humidity requirements as provided in the FDA approved drug product labeling or the *United States Pharmacopeia* (USP).

(E) Temperatures in drug storage areas must be recorded and reviewed at least once each day the facility is in operation. Alternatively, a continuous temperature monitoring system may be used if the system maintains ongoing documentation of temperature recordings that alerts the manager-in-charge or designated facility staff when temperatures are outside of the required range.

(F) 3PLs located in this state may only purchase or receive legend drugs and/or drug related devices from an entity licensed as a Missouri drug distributor, third-party logistics provider, or drug outsourcer.

(G) No outdated, misbranded, or adulterated drugs or devices may be dispensed or maintained within the facility's active inventory, including prescription and related nonprescription items. Outdated, misbranded, or adulterated medication must be quarantined in a clearly identified segregated area and maintained separately from drugs intended for distribution or being processed for distribution.

(H) No third-party logistics provider with physical facilities located in the state of Missouri shall knowingly purchase or receive legend drugs and/or drug related devices from a wholesale drug distributor, third-party logistics provider, drug outsourcer, or pharmacy not licensed or registered by the board.

(I) Drugs held for distribution must be stored in a secure area where only authorized personnel have access to them. A list of all individuals who have independent access to drug storage areas must be maintained. The list must be maintained for three (3) years and must be readily retrievable on request of the board or the board's authorized designee.

(J) Medication may not be stored on the floor. Drug products must be raised above floor level and placed on a pallet or similar device.

(K) The outside shipping container of received medication must be visually examined for identity and for container and content integrity to prevent the acceptance or distribution of any contaminated, adulterated, or otherwise unfit medication. Any prescription drug whose immediate or sealed outer container or sealed secondary container has been opened, used, or improperly compromised must be quarantined and physically separated from the facility's active inventory.

(L) Drugs shipped for distribution or further use must be carefully inspected prior to shipping/distribution for identity and to ensure prescription drugs that have been damaged in storage or held under improper conditions are not distributed. Licensees shall maintain and follow security procedures for delivering drugs from the facility to the destination site.

(M) Drug products must be labeled as required by the manufacturer and state and federal law, including, section 338.059.2, RSMo.

(N) Third-party logistics providers must develop and implement written policies and procedures to ensure the safe and appropriate delivery of prescription drugs within the temperature requirements recommended by the manufacturer or the *United States Pharmacopeia* (USP).

(O) For returned medication, licensees must consider the conditions under which the medication has been held, stored, or shipped, the condition of the drug and its container/carton and any other relevant factor that may reflect on the drug's fitness for further use or distribution. If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity.

(P) Licensees shall file a written or electronic report with the board within seventy-two (72) hours after discovery of:

1. Any suspected criminal activity related to or diversion of a prescription drug or device; and

2. Any real or suspected counterfeit, contraband, or illegitimate prescription drug or drug-related device. The report must include the name of the drug, quantity, and lot number(s). Recalls initiated by the Food and Drug Administration (FDA) or by a supplier

licensed with the state of Missouri do not have to be reported, unless otherwise required by state and federal law.

(5) Policies and Procedures. 3PLs must maintain and follow current and accurate policies and procedures governing all aspects of the facility's 3PL activities. Policies and procedures must be physically or electronically maintained at the facility, provided the policies/procedures are immediately retrievable at the request of the board or the board's authorized designee.

(6) Agents or employees of a licensed third-party logistics provider may have legend drugs in their custody if they are acting in the usual course of business or employment and their names and addresses and the addresses of all sites where drugs are stored have been provided to the board. Drugs stored and transported by agents or employees of a third-party logistics provider must be maintained in accordance with manufacturer or USP guidelines and must be free of contamination, deterioration, or adulteration.

(7) Record-Keeping. 3PL records must be accurately maintained in compliance with state and federal law. Additionally, licensees must maintain inventories and records of all transactions regarding the receipt, distribution, or other disposition of prescription drugs or prescription drug-related devices.

(A) The following records must be maintained:

1. The date drugs or drug-related devices are received or distributed;

2. The identity and quantity of drugs or drug-related devices received, distributed, or disposed of;

3. The identity of any suppliers of prescription drugs or drug-related items, including the name and principal address of the seller/transferor and the address of the location where the drug/drug-related item was shipped from;

4. The name and address of any recipients of prescription drugs or drug-related items; and

5. Any records required by state and federal law.

(B) Unless otherwise provided by law, records required by Chapter 338 or this rule must be maintained for three (3) years. Records may be manually or electronically maintained, provided the record is readily retrievable and available for inspection, photographing, or duplication at the request of the board or the board's authorized designee or at the request of authorized federal, state, or local law enforcement officials. Records maintained offsite and not electronically retrievable at the 3PL facility must be made available for inspection within two (2) working days of a request by the board or an authorized board designee.

(8) Exemptions. At its discretion, the board may grant an exemption to the facility requirements of this rule for a time period designated by the board if such exemption is not contrary to law and the exemption will provide equal or greater protection of the public safety, health, or welfare. Exemption requests must be submitted in writing and identify the specific exemption requested, the grounds for exemption, the requested exemption length, and proposed procedures or safeguards for protecting the public safety, health, or welfare if the exemption is approved.

AUTHORITY: sections 338.140, 338.150, 338.280, and 338.350, RSMo 2016, and sections 338.315, 338.330, 338.333, 338.337, and 338.340, RSMo Supp. 2018. Emergency rule filed Nov. 28, 2018, effective Dec. 8, 2018, expired June 5, 2019. Original rule filed Nov. 28, 2018, effective May 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011, 2013; 338.280, RSMo 1951, amended 1971, 1981; 338.315, RSMo 1989, amended 2011, 2012, 2014, 2018; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; 338.333, RSMo 1989, amended 2010, 2012, 2018; 338.337, RSMo 1989, amended 2009, 2010, 2018; 338.340, RSMo 1989, amended 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-8.050 Inspection Exemptions

PURPOSE: This rule defines requirements for inspection standards for drug outsourcers and third-party logistics providers and standards for inspection exemptions for third-party logistic providers.

(1) Board inspections of third-party logistics providers and drug outsourcers will be conducted in accordance with Chapter 338, RSMo. At the discretion of the board, a third-party logistics provider facility that has been inspected by the United States Food and Drug Administration (FDA) within the previous two (2) years may be exempt from inspection by the board if the FDA inspection(s) resulted in a satisfactory rating. The FDA inspection must be a full inspection of all facility operations and procedures.

(2) The board may terminate an exemption under this section if deemed necessary or appropriate, if the last full FDA inspection is two (2) years old or greater or if any subsequent facility inspection by a state or federal entity results in less than a satisfactory rating.

(A) For purposes of this rule, a less than satisfactory rating includes, but is not limited to, any documented deficiency related to third-party logistic provider operations, drug distribution, repackaging, labeling, quality control, environmental policies/procedures, or controlled substances. Deficiencies include any statement that is a part of a federal compliance, inspection or observational report with or without sanctions, penalties, fines, or discipline imposed.

(B) Licensees granted an inspection exemption under this section shall notify the board if any inspection conducted by the FDA or the Drug Enforcement Administration results in less than a satisfactory rating as defined in subsection (2)(A).

AUTHORITY: sections 338.140, 338.150, 338.280, and 338.350, RSMo 2016, and sections 338.315, 338.330, 338.333, 338.337, and 338.340, RSMo Supp. 2018. Original rule filed Nov. 28, 2018, effective May 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011, 2013; 338.280, RSMo 1951, amended 1971, 1981; 338.315, RSMo 1989, amended 2011, 2012, 2014, 2018; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; 338.333, RSMo 1989, amended 2010, 2012, 2018; 338.337, RSMo 1989, amended 2009, 2010, 2018; 338.340, RSMo 1989, amended 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

20 CSR 2220-8.060 Termination of Business

PURPOSE: This rule establishes guidelines for terminating business as a third-party logistics provider or drug outsourcer.

(1) A licensed third-party logistics provider or drug outsourcer must notify the board within fifteen (15) days after terminating business in Missouri. Notification must be in writing or on a form provided by the board and include the following information:

(A) The name, address, license number, and effective date of closure;

(B) The name, address, and license number of the entity to which any of the stock/inventory will be transferred; and

(C) The name and address of the location where records required to be maintained by law will be transferred.

(2) Licensees terminating business may transfer all drugs and records in accordance with the following:

(A) Misbranded, outdated, or adulterated

drugs may not be transferred, except for purposes of proper disposal;

(B) The entity's Missouri license must be returned to the board either in person or by registered or certified mail; and

(C) Any records transferred to an unlicensed location must be retrievable for board review within seven (7) working days of a request made by an authorized official of the board.

(3) This rule does not preempt any other laws or regulations governing third-party logistic (3PL) or drug outsourcer licensure, change of ownership, change of location, or change of name.

AUTHORITY: sections 338.140, 338.150, 338.280, and 338.350, RSMo 2016, and sections 338.315, 338.330, 338.333, 338.337, and 338.340, RSMo Supp. 2018. Original rule filed Nov. 28, 2018, effective May 30, 2019.*

**Original authority: 338.140, RSMo 1939, amended 1981, 1989, 1997, 2011; 338.150, RSMo 1939, amended 1951, 1961, 1980, 1981, 2011, 2013; 338.280, RSMo 1951, amended 1971, 1981; 338.315, RSMo 1989, amended 2011, 2012, 2014, 2018; 338.330, RSMo 1989, amended 1993, 1998, 2011, 2018; 338.333, RSMo 1989, amended 2010, 2012, 2018; 338.337, RSMo 1989, amended 2009, 2010, 2018; 338.340, RSMo 1989, amended 2018; and 338.350, RSMo 1989, amended 1993, 1995.*

Chapter 195
BNDD Statutes
(Excerpts)

CHAPTER 195 INDEX

195.010. Definitions.

The following words and phrases as used in this chapter and chapter 579, unless the context otherwise requires, mean:

(1) "Acute pain", pain, whether resulting from disease, accidental or intentional trauma, or other causes, that the practitioner reasonably expects to last only a short period of time. Acute pain shall not include chronic pain, pain being treated as part of cancer care, hospice or other end-of-life care, or medication-assisted treatment for substance use disorders;

(2) "Addict", a person who habitually uses one or more controlled substances to such an extent as to create a tolerance for such drugs, and who does not have a medical need for such drugs, or who is so far addicted to the use of such drugs as to have lost the power of self-control with reference to his or her addiction;

(3) "Administer", to apply a controlled substance, whether by injection, inhalation, ingestion, or any other means, directly to the body of a patient or research subject by:

(a) A practitioner (or, in his or her presence, by his or her authorized agent); or

(b) The patient or research subject at the direction and in the presence of the practitioner;

(4) "Agent", an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. The term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman while acting in the usual and lawful course of the carrier's or warehouseman's business;

(5) "Attorney for the state", any prosecuting attorney, circuit attorney, or attorney general authorized to investigate, commence and prosecute an action under this chapter;

(6) "Controlled substance", a drug, substance, or immediate precursor in Schedules I through V listed in this chapter;

(7) "Controlled substance analogue", a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and:

(a) Which has a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance included in Schedule I or II; or

(b) With respect to a particular individual, which that individual represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance included in Schedule I or II. The term does not include a controlled substance; any substance for which there is an approved new drug application; any substance for which an exemption is in effect for investigational use, for a particular person, under Section 505 of the federal Food, Drug and Cosmetic Act (21 U.S.C. Section 355) to the extent conduct with respect to the substance is pursuant to the exemption; or any substance to the extent not intended for human consumption before such an exemption takes effect with respect to the substance;

(8) "Counterfeit substance", a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the substance;

(9) "Deliver" or "delivery", the actual, constructive, or attempted transfer from one person to another of drug paraphernalia or of a controlled substance, or an imitation controlled substance, whether or not there is an agency relationship, and includes a sale;

(10) "Dentist", a person authorized by law to practice dentistry in this state;

(11) "Depressant or stimulant substance":

(a) A drug containing any quantity of barbituric acid or any of the salts of barbituric acid or any derivative of barbituric acid which has been designated by the United States Secretary of Health and Human Services as habit forming under 21 U.S.C. Section 352(d);

(b) A drug containing any quantity of:

a. Amphetamine or any of its isomers;

b. Any salt of amphetamine or any salt of an isomer of amphetamine; or

c. Any substance the United States Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system;

(c) Lysergic acid diethylamide; or

(d) Any drug containing any quantity of a substance that the United States Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect;

(12) "Dispense", to deliver a narcotic or controlled dangerous drug to an ultimate user or research subject by or pursuant

to the lawful order of a practitioner including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for such delivery. “Dispenser” means a practitioner who dispenses;
(13) “Distribute”, to deliver other than by administering or dispensing a controlled substance;
(14) “Distributor”, a person who distributes;
(15) “Drug”:
(a) Substances recognized as drugs in the official United States Pharmacopoeia, Official Homeopathic Pharmacopoeia of the United States, or Official National Formulary, or any supplement to any of them;
(b) Substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or animals;
(c) Substances, other than food, intended to affect the structure or any function of the body of humans or animals; and
(d) Substances intended for use as a component of any article specified in this subdivision. It does not include devices or their components, parts or accessories;
(16) “Drug-dependent person”, a person who is using a controlled substance and who is in a state of psychic or physical dependence, or both, arising from the use of such substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence;
(17) “Drug enforcement agency”, the Drug Enforcement Administration in the United States Department of Justice, or its successor agency;
(18) “Drug paraphernalia”, all equipment, products, substances and materials of any kind which are used, intended for use, or designed for use, in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, storing, containing, concealing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance or an imitation controlled substance in violation of this chapter or chapter 579. It includes, but is not limited to:
(a) Kits used, intended for use, or designed for use in planting, propagating, cultivating, growing or harvesting of any species of plant which is a controlled substance or from which a controlled substance can be derived;
(b) Kits used, intended for use, or designed for use in manufacturing, compounding, converting, producing, processing, or preparing controlled substances or imitation controlled substances;
(c) Isomerization devices used, intended for use, or designed for use in increasing the potency of any species of plant which is a controlled substance or an imitation controlled substance;
(d) Testing equipment used, intended for use, or designed for use in identifying, or in analyzing the strength, effectiveness or purity of controlled substances or imitation controlled substances;
(e) Scales and balances used, intended for use, or designed for use in weighing or measuring controlled substances or imitation controlled substances;
(f) Dilutents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose and lactose, used, intended for use, or designed for use in cutting controlled substances or imitation controlled substances;
(g) Separation gins and sifters used, intended for use, or designed for use in removing twigs and seeds from, or in otherwise cleaning or refining, marijuana;
(h) Blenders, bowls, containers, spoons and mixing devices used, intended for use, or designed for use in compounding controlled substances or imitation controlled substances;
(i) Capsules, balloons, envelopes and other containers used, intended for use, or designed for use in packaging small quantities of controlled substances or imitation controlled substances;
(j) Containers and other objects used, intended for use, or designed for use in storing or concealing controlled substances or imitation controlled substances;
(k) Hypodermic syringes, needles and other objects used, intended for use, or designed for use in parenterally injecting controlled substances or imitation controlled substances into the human body;
(l) Objects used, intended for use, or designed for use in ingesting, inhaling, or otherwise introducing marijuana, cocaine, hashish, or hashish oil into the human body, such as:
a. Metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls;
b. Water pipes;
c. Carburetion tubes and devices;
d. Smoking and carburetion masks;
e. Roach clips meaning objects used to hold burning material, such as a marijuana cigarette, that has become too small or too short to be held in the hand;
f. Miniature cocaine spoons and cocaine vials;
g. Chamber pipes;
h. Carburetor pipes;
i. Electric pipes;
j. Air-driven pipes;
k. Chillums;

l. Bongs;

m. Ice pipes or chillers;

(m) Substances used, intended for use, or designed for use in the manufacture of a controlled substance.

In determining whether an object, product, substance or material is drug paraphernalia, a court or other authority should consider, in addition to all other logically relevant factors, the following:

a. Statements by an owner or by anyone in control of the object concerning its use;

b. Prior convictions, if any, of an owner, or of anyone in control of the object, under any state or federal law relating to any controlled substance or imitation controlled substance;

c. The proximity of the object, in time and space, to a direct violation of this chapter or chapter 579;

d. The proximity of the object to controlled substances or imitation controlled substances;

e. The existence of any residue of controlled substances or imitation controlled substances on the object;

f. Direct or circumstantial evidence of the intent of an owner, or of anyone in control of the object, to deliver it to persons who he or she knows, or should reasonably know, intend to use the object to facilitate a violation of this chapter or chapter 579; the innocence of an owner, or of anyone in control of the object, as to direct violation of this chapter or chapter 579 shall not prevent a finding that the object is intended for use, or designed for use as drug paraphernalia;

g. Instructions, oral or written, provided with the object concerning its use;

h. Descriptive materials accompanying the object which explain or depict its use;

i. National or local advertising concerning its use;

j. The manner in which the object is displayed for sale;

k. Whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products;

l. Direct or circumstantial evidence of the ratio of sales of the object to the total sales of the business enterprise;

m. The existence and scope of legitimate uses for the object in the community;

n. Expert testimony concerning its use;

o. The quantity, form or packaging of the product, substance or material in relation to the quantity, form or packaging associated with any legitimate use for the product, substance or material;

(19) "Federal narcotic laws", the laws of the United States relating to controlled substances;

(20) "Hospital", a place devoted primarily to the maintenance and operation of facilities for the diagnosis, treatment or care, for not less than twenty-four hours in any week, of three or more nonrelated individuals suffering from illness, disease, injury, deformity or other abnormal physical conditions; or a place devoted primarily to provide, for not less than twenty-four consecutive hours in any week, medical or nursing care for three or more nonrelated individuals. The term hospital does not include convalescent, nursing, shelter or boarding homes as defined in chapter 198;

(21) "Illegal industrial hemp":

(a) All nonseed parts and varieties of the Cannabis sativa L. plant, growing or not, that contain an average delta-9 tetrahydrocannabinol (THC) concentration exceeding three-tenths of one percent on a dry weight basis;

(b) Illegal industrial hemp shall be destroyed in the most effective manner possible, and such destruction shall be verified by the Missouri state highway patrol;

(22) "Immediate precursor", a substance which:

(a) The state department of health and senior services has found to be and by rule designates as being the principal compound commonly used or produced primarily for use in the manufacture of a controlled substance;

(b) Is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance; and

(c) The control of which is necessary to prevent, curtail or limit the manufacture of the controlled substance;

(23) "Imitation controlled substance", a substance that is not a controlled substance, which by dosage unit appearance (including color, shape, size and markings), or by representations made, would lead a reasonable person to believe that the substance is a controlled substance. In determining whether the substance is an imitation controlled substance the court or authority concerned should consider, in addition to all other logically relevant factors, the following:

(a) Whether the substance was approved by the federal Food and Drug Administration for over-the-counter (nonprescription or nonlegend) sales and was sold in the federal Food and Drug Administration-approved package, with the federal Food and Drug Administration-approved labeling information;

(b) Statements made by an owner or by anyone else in control of the substance concerning the nature of the substance, or its use or effect;

(c) Whether the substance is packaged in a manner normally used for illicit controlled substances;

(d) Prior convictions, if any, of an owner, or anyone in control of the object, under state or federal law related to controlled substances or fraud;

(e) The proximity of the substances to controlled substances;

(f) Whether the consideration tendered in exchange for the noncontrolled substance substantially exceeds the reasonable value of the substance considering the actual chemical composition of the substance and, where applicable, the price at which over-the-counter substances of like chemical composition sell. An imitation controlled substance does not include a placebo or registered investigational drug either of which was manufactured, distributed, possessed or delivered in the ordinary course of professional practice or research;

(24) “Industrial hemp”:

(a) All nonseed parts and varieties of the Cannabis sativa L. plant, growing or not, that contain an average delta-9 tetrahydrocannabinol (THC) concentration that does not exceed three-tenths of one percent on a dry weight basis or the maximum concentration allowed under federal law, whichever is greater;

(b) Any Cannabis sativa L. seed that is part of a growing crop, retained by a grower for future planting, or used for processing into or use as agricultural hemp seed;

(c) Industrial hemp includes industrial hemp commodities and products and topical or ingestible animal and consumer products derived from industrial hemp with a delta-9 tetrahydrocannabinol concentration of not more than three-tenths of one percent on a dry weight basis;

(25) “Initial prescription”, a prescription issued to a patient who has never previously been issued a prescription for the drug or its pharmaceutical equivalent or who was previously issued a prescription for the drug or its pharmaceutical equivalent, but the date on which the current prescription is being issued is more than five months after the date the patient last used or was administered the drug or its equivalent;

(26) “Laboratory”, a laboratory approved by the department of health and senior services as proper to be entrusted with the custody of controlled substances but does not include a pharmacist who compounds controlled substances to be sold or dispensed on prescriptions;

(27) “Manufacture”, the production, preparation, propagation, compounding or processing of drug paraphernalia or of a controlled substance, or an imitation controlled substance, either directly or by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include the preparation or compounding of a controlled substance or an imitation controlled substance or the preparation, compounding, packaging or labeling of a narcotic or dangerous drug:

(a) By a practitioner as an incident to his or her administering or dispensing of a controlled substance or an imitation controlled substance in the course of his or her professional practice; or

(b) By a practitioner or his or her authorized agent under his or her supervision, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale;

(28) “Marijuana”, all parts of the plant genus Cannabis in any species or form thereof, including, but not limited to Cannabis Sativa L., except industrial hemp, Cannabis Indica, Cannabis Americana, Cannabis Ruderalis, and Cannabis Gigantea, whether growing or not, the seeds thereof, the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil or cake, or the sterilized seed of the plant which is incapable of germination;

(29) “Methamphetamine precursor drug”, any drug containing ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers;

(30) “Narcotic drug”, any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical analysis:

(a) Opium, opiate, and any derivative, of opium or opiate, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation. The term does not include the isoquinoline alkaloids of opium;

(b) Coca leaves, but not including extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(c) Cocaine or any salt, isomer, or salt of isomer thereof;

(d) Ecgonine, or any derivative, salt, isomer, or salt of isomer thereof;

(e) Any compound, mixture, or preparation containing any quantity of any substance referred to in paragraphs (a) to (d) of this subdivision;

(31) “Official written order”, an order written on a form provided for that purpose by the United States Commissioner of Narcotics, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided, then on an official form provided for that purpose by the department of health and senior services;

(32) “Opiate” or “opioid”, any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. The term includes its racemic and levorotatory forms. It does not include, unless specifically controlled under section 195.017, the dextrorotatory isomer of 3-methoxy-n-methyl-morphinan and its salts (dextromethorphan);

(33) “Opium poppy”, the plant of the species Papaver somniferum L., except its seeds;

(34) “Over-the-counter sale”, a retail sale licensed pursuant to chapter 144 of a drug other than a controlled substance;

(35) “Person”, an individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership, joint venture, association, or any other legal or commercial entity;

(36) “Pharmacist”, a licensed pharmacist as defined by the laws of this state, and where the context so requires, the owner of a store or other place of business where controlled substances are compounded or dispensed by a licensed

pharmacist; but nothing in this chapter shall be construed as conferring on a person who is not registered nor licensed as a pharmacist any authority, right or privilege that is not granted to him by the pharmacy laws of this state;

(37) "Poppy straw", all parts, except the seeds, of the opium poppy, after mowing;

(38) "Possessed" or "possessing a controlled substance", a person, with the knowledge of the presence and nature of a substance, has actual or constructive possession of the substance. A person has actual possession if he has the substance on his or her person or within easy reach and convenient control. A person who, although not in actual possession, has the power and the intention at a given time to exercise dominion or control over the substance either directly or through another person or persons is in constructive possession of it. Possession may also be sole or joint. If one person alone has possession of a substance possession is sole. If two or more persons share possession of a substance, possession is joint;

(39) "Practitioner", a physician, dentist, optometrist, podiatrist, veterinarian, scientific investigator, pharmacy, hospital or other person licensed, registered or otherwise permitted by this state to distribute, dispense, conduct research with respect to or administer or to use in teaching or chemical analysis, a controlled substance in the course of professional practice or research in this state, or a pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or administer a controlled substance in the course of professional practice or research;

(40) "Production", includes the manufacture, planting, cultivation, growing, or harvesting of drug paraphernalia or of a controlled substance or an imitation controlled substance;

(41) "Registry number", the number assigned to each person registered under the federal controlled substances laws;

(42) "Sale", includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as principal, proprietor, agent, servant or employee;

(43) "State" when applied to a part of the United States, includes any state, district, commonwealth, territory, insular possession thereof, and any area subject to the legal authority of the United States of America;

(44) "Synthetic cannabinoid", includes unless specifically excepted or unless listed in another schedule, any natural or synthetic material, compound, mixture, or preparation that contains any quantity of a substance that is a cannabinoid receptor agonist, including but not limited to any substance listed in paragraph (ll) of subdivision (4) of subsection 2 of section 195.017 and any analogues; homologues; isomers, whether optical, positional, or geometric; esters; ethers; salts; and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, or salts is possible within the specific chemical designation, however, it shall not include any approved pharmaceutical authorized by the United States Food and Drug Administration;

(45) "Ultimate user", a person who lawfully possesses a controlled substance or an imitation controlled substance for his or her own use or for the use of a member of his or her household or immediate family, regardless of whether they live in the same household, or for administering to an animal owned by him or by a member of his or her household. For purposes of this section, the phrase "immediate family" means a husband, wife, parent, child, sibling, stepparent, stepchild, stepbrother, stepsister, grandparent, or grandchild;

(46) "Wholesaler", a person who supplies drug paraphernalia or controlled substances or imitation controlled substances that he himself has not produced or prepared, on official written orders, but not on prescriptions.

(RSMo 1939 § 9832, A.L. 1945 p. 957, A.L. 1953 p. 619, A.L. 1957 p. 679, A.L. 1971 H.B. 69, A.L. 1975 H.B. 438, A.L. 1982 S.B. 522, A.L. 1989 S.B. 215 & 58, A.L. 1997 H.B. 635, A.L. 1998 H.B. 1147, et al., A.L. 2001 H.B. 471 merged with S.B. 89 & 37, A.L. 2011 H.B. 641, A.L. 2014 S.B. 491, A.L. 2018 H.B. 2034 merged with S.B. 826)

(1976) "Cannabis sativa" and "marihuana" are synonymous terms and defendant charged with sale of "cannabis sativa" could be convicted of sale of controlled substance. State v. Simpson (A.), 534 S.W.2d 568.

(1976) Term "marihuana" held synonymous with cannabis even under 1971 version of this section. State v. Morrow (A.), 535 S.W.2d 539.

(1976) Conviction cannot be had for possession of "hashish" since it by definition is a marihuana derivative, conviction must be for possession of marihuana. State v. Randall (A.), 540 S.W.2d 156.

(1987) Even though no money was exchanged before defendant was arrested for selling marijuana, instruction to jury on offense of selling marijuana was proper since acts of defendant constitute "sale" as defined by this section where defendant had made an agreement with undercover officers to deliver a set quantity for a set price and the defendant then delivered the marijuana to such officers. State v. McClintic, 731 S.W.2d 853 (Mo. App.).

195.015. Authority to control.

1. The department of health and senior services shall administer this chapter and may add substances to the schedules after public notice and hearing. In making a determination regarding a substance, the department of health and senior services shall consider the following:

(1) The actual or relative potential for abuse;

(2) The scientific evidence of its pharmacological effect, if known;

(3) The state of current scientific knowledge regarding the substance;

(4) The history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;
(6) The risk to the public health;
(7) The potential of the substance to produce psychic or physiological dependence liability; and
(8) Whether the substance is an immediate precursor of a substance already controlled under this chapter.

2. After considering the factors enumerated in subsection 1 of this section the department of health and senior services shall make findings with respect thereto and issue a rule controlling the substance if it finds the substance has a potential for abuse.

3. If the department of health and senior services designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

4. If any substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice thereof is given to the department of health and senior services, the department of health and senior services shall similarly control the substance under this chapter and shall submit emergency rules to the secretary of state under section 536.025 within thirty days of publication in the federal register of a final order designating a substance as a controlled substance or rescheduling or deleting a substance, unless within that thirty-day period, the department of health and senior services objects to inclusion, rescheduling, or deletion. In that case, the department of health and senior services shall publish the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the department of health and senior services shall publish its decision, which shall be final unless altered by statute. Upon publication of objection to inclusion, rescheduling or deletion under this chapter by the department of health and senior services, control under this chapter is stayed as to the substance in question until the department of health and senior services publishes its decision. If the department promulgates emergency rules under this subsection, such rules may, notwithstanding the provisions of subsection 7 of section 536.025, remain in effect until the general assembly concludes its next regular session following the imposition of any such rules. The department shall clearly state if the rules shall be in effect pursuant to this subsection or subsection 7 of section 536.025 in the emergency statement filed with the secretary of state.

5. The department of health and senior services shall exclude any nonnarcotic substance from a schedule if such substance may, under the federal Food, Drug, and Cosmetic Act and the law of this state, be lawfully sold over the counter without a prescription.

6. The department of health and senior services shall prepare a list of all drugs falling within the purview of controlled substances. Upon preparation, a copy of the list shall be filed in the office of the secretary of state.

(L. 1971 H.B. 69, A.L. 1989 S.B. 215 & 58, A.L. 2014 S.B. 491, A.L. 2020 H.B. 1896)
(1975) Rescheduling of a controlled substance from schedule III to schedule II by division of health after same action on the federal level was proper and defendant's contention that the division had no authority to subtract or remove a substance was held invalid. State v. Winters (A.), 525 S.W.2d 417.
(1982) Statute providing that if substance is designated as controlled substance under federal law and notice thereof is given to division of health, the division shall also control substance unless it objects and statute does not result in an unlawful delegation of legislative authority. State v. Thompson (Mo.), 627 S.W.2d 298.

195.016. Nomenclature.

The controlled substances listed or to be listed in the schedules in section 195.017 are included by whatever official, common, usual, chemical, or trade name designated.

(L. 1971 H.B. 69, A.L. 1989 S.B. 215 & 58, A.L. 2014 S.B. 491)
Effective 1-01-17

195.017. Substances, how placed in schedules — list of scheduled substances — publication of schedules annually — electronic log of transactions to be maintained, when — certain products to be located behind pharmacy counter — exemption from requirements, when — rulemaking authority.

1. The department of health and senior services shall place a substance in Schedule I if it finds that the substance:
(1) Has high potential for abuse; and
(2) Has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.

2. Schedule I:
(1) The controlled substances listed in this subsection are included in Schedule I;
(2) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:
(a) Acetyl-alpha-methylfentanyl (N-(1-(1-methyl-2-phenethyl)-4-piperidinyl)-N-phenylacetamide);
(b) Acetylmethadol;
(c) Acetyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide);
(d) Acryl fentanyl (-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide);

(e) AH-7921(3,4-dichloro-N-[(1-dimethylamino) cyclohexylmethyl] benzamide);
(f) Allylprodine;
(g) Alphacetylmethadol (except levoalphacetylmethadol, also known as levo-alpha-acetylmethadol levothadyl acetate or LAAM);
(h) Alphameprodine;
(i) Alphamethadol;
(j) Alpha-methylfentanyl (N-1-(alphamethyl-beta-phenyl) ethyl-4-piperidyl) propionanilide; 1-(1-methyl-2-phenylethyl)-4 ((N-propanilido) piperidine);
(k) Alpha-methylthiofentanyl (N-(1-methyl-2-(2-thienyl) ethyl-4-piperidinyl)-N-phenylpropanamide);
(l) Benzethidine;
(m) Betacetylmethadol;
(n) Beta-hydroxyfentanyl (N-(1-(2-hydroxy-2-phenethyl)-4-piperidinyl)-N-phenylpropanamide);
(o) Beta-hydroxy-3-methylfentanyl (N-(1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl)-N-phenylpropanamide);
(p) Betameprodine;
(q) Betamethadol;
(r) Betaprodine;
(s) Clonitazene;
(t) Dextromoramide;
(u) Diampromide;
(v) Cyclopropyl fentanyl;
(w) Diethylthiambutene;
(x) Difenoxin;
(y) Dimenoxadol;
(z) Dimepheptanol;
(aa) Dimethylthiambutene;
(bb) Dioxaphetyl butyrate;
(cc) Dipipanone;
(dd) Ethylmethylthiambutene;
(ee) Etonitazene;
(ff) Etoxeridine;
(gg) 4-fluoroisobutyryl fentanyl -(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide;
(hh) Furanyl fentanyl -(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide;
(ii) Furethidine;
(jj) Hydroxypethidine;
(kk) Ketobemidone;
(ll) Levomoramide;
(mm) Levophenacylmorphan;
(nn) 3-Methylfentanyl (N-(3-methyl-1-(2-phenylethyl)-4-piperidyl)-N-phenylproanamide), its optical and geometric isomers, salts, and salts of isomers;
(oo) 3-Methylthiofentanyl (N-((3-methyl-1-(2-thienyl)ethyl-4-piperidinyl)-N-phenylpropanamide);
(pp) Methoxyacetyl fentanyl (2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide);
(qq) Morpheridine;
(rr) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);
(ss) MT-45(1-cyclohexyl-4-(1,2-diphenylethyl) piperazine);
(tt) Noracymethadol;
(uu) Norlevorphanol;
(vv) Normethadone;
(ww) Norpipanone;
(xx) Ocfentanil N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide;
(yy) Ortho-fluorofentanyl (N-2-(1-phenethylpiperidin-yl)propionamide); other name 2-fluorofentanyl;
(zz) para-fluorobutyryl fentanyl (N-4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide;
(aaa) Para-fluorofentanyl (N-(4-fluorophenyl)-N-(1-(2-phenethyl)-4-piperidinyl) propanamide;
(bbb) PEPAP (1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine);
(ccc) Phenadoxone;
(ddd) Phenampromide;
(eee) Phenomorphan;
(fff) Phenoperidine;
(ggg) Piritramide;
(hhh) Proheptazine;
(iii) Properidine;

(jjj) Propiram;
(kkk) Racemoramide;
(lll) Tetrahydrofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide);
(mmm) Thiofentanyl (-phenyl-N-(1-(2-thienyl)ethyl-4-piperidinyl)-propanamide;
(nnn) Tilidine;
(ooo) Trimeperidine;

(3) Any of the following opium derivatives, their salts, isomers and salts of isomers unless specifically excepted, whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

(a) Acetorphine;
(b) Acetyldihydrocodeine;
(c) Benzylmorphine;
(d) Codeine methylbromide;
(e) Codeine-N-Oxide;
(f) Cyprenorphine;
(g) Desomorphine;
(h) Dihydromorphine;
(i) Drotebanol;
(j) Etorphine (except hydrochloride salt);
(k) Heroin;
(l) Hydromorphinol;
(m) Methyldesorphine;
(n) Methyldihydromorphine;
(o) Morphine methylbromide;
(p) Morphine methylsulfonate;
(q) Morphine-N-Oxide;
(r) Myrophine;
(s) Nicocodeine;
(t) Nicomorphine;
(u) Normorphine;
(v) Pholcodine;
(w) Thebacon;

(4) Any of the following opiate similar synthetic substances scheduled by the U.S. Drug Enforcement Administration as substances that share a pharmacological profile similar to fentanyl, morphine, and other synthetic opioids, unless specifically excepted or unless listed in another schedule:

(a) Butyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide);
(b) U-47700 (3,4-Dichloro-N-[2-(dimethylamino) cyclohexyl]--methyl benzamide).

(5) Any material, compound, mixture or preparation which contains any quantity of the following hallucinogenic substances, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) Alpha-ethyltryptamine;
(b) 4-bromo-2,5-dimethoxyamphetamine;
(c) 4-bromo-2,5-dimethoxyphenethylamine;
(d) 2,5-dimethoxyamphetamine;
(e) 2,5-dimethoxy-4-ethylamphetamine;
(f) 2,5-dimethoxy-4-(n)-propylthiophenethylamine;
(g) 2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine;
(h) 2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine;
(i) 2-(2,5-Dimethoxy-4-methylphenyl) ethanamine;
(j) 2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine;
(k) 2-(2,5-Dimethoxyphenyl) ethanamine;
(l) 2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine;
(m) 2-(4-Ethylthio-2,5-dimethoxyphenyl) ethanamine;
(n) 2-(4-Iodo-2,5-dimethoxyphenyl) ethanamine;
(o) 2-(4-Isopropylthio)-2,5-dimethoxyphenyl) ethanamine;
(p) 4-methoxyamphetamine;
(q) 5-methoxy-3,4-methylenedioxyamphetamine;
(r) 4-methyl-2, 5-dimethoxyamphetamine;
(s) 3,4-methylenedioxyamphetamine;
(t) 3,4-methylenedioxymethamphetamine;
(u) 3,4-methylenedioxy-N-ethylamphetamine;

(v) N-hydroxy-3, 4-methylenedioxyamphetamine;
(w) 3,4,5-trimethoxyamphetamine;
(x) 5-MeO-DMT or 5-methoxy-N,N-dimethyltryptamine;
(y) Alpha-methyltryptamine;
(z) Bufotenine;
(aa) Diethyltryptamine;
(bb) Dimethyltryptamine;
(cc) 5-methoxy-N,N-diisopropyltryptamine;
(dd) Ibogaine;
(ee) Lysergic acid diethylamide;
(ff) Marijuana or marihuana, except industrial hemp;
(gg) Mescaline;
(hh) Parahexyl;
(ii) Peyote, to include all parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seed or extracts;
(jj) N-ethyl-3-piperidyl benzilate;
(kk) N-methyl-3-piperidyl benzilate;
(ll) Psilocybin;
(mm) Psilocyn;
(nn) Tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (cannabis plant), except industrial hemp, as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant, or synthetic substances, derivatives and their isomers, or both, with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:
a. 1 cis or trans tetrahydrocannabinol and their optical isomers;
b. 6 cis or trans tetrahydrocannabinol and their optical isomers;
c. 3,4 cis or trans tetrahydrocannabinol and their optical isomers;
d. Any compounds of these structures, regardless of numerical designation of atomic positions covered;
(oo) Ethylamine analog of phencyclidine;
(pp) Pyrrolidine analog of phencyclidine;
(qq) Thiophene analog of phencyclidine;
(rr) 1-[1-(2-thienyl)cyclohexyl]pyrrolidine;
(ss) Salvia divinorum;
(tt) Salvinorin A;
(uu) Synthetic cannabinoids:
a. Any compound structurally derived from 3-(1-naphthoyl)indole or 1H-indol-3-yl-(1-naphthyl)methane by substitution at the nitrogen atom of the indole ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent, whether or not substituted in the naphthyl ring to any extent. Including, but not limited to:
(i) AM2201, or 1-(5-fluoropentyl)-3-(1-naphthoyl)indole;
(ii) JWH-007, or 1-pentyl-2-methyl-3-(1-naphthoyl)indole;
(iii) JWH-015, or 1-propyl-2-methyl-3-(1-naphthoyl)indole;
(iv) JWH-018, or 1-pentyl-3-(1-naphthoyl)indole;
(v) JWH-019, or 1-hexyl-3-(1-naphthoyl)indole;
(vi) JWH-073, or 1-butyl-3-(1-naphthoyl)indole;
(vii) JWH-081, or 1-pentyl-3-(4-methoxy-1-naphthoyl)indole;
(viii) JWH-098, or 1-pentyl-2-methyl-3-(4-methoxy-1-naphthoyl)indole;
(ix) JWH-122, or 1-pentyl-3-(4-methyl-1-naphthoyl)indole;
(x) JWH-164, or 1-pentyl-3-(7-methoxy-1-naphthoyl)indole;
(xi) JWH-200, or 1-(2-(4-(morpholinyl)ethyl))-3-(1-naphthoyl)indole;
(xii) JWH-210, or 1-pentyl-3-(4-ethyl-1-naphthoyl)indole;
(xiii) JWH-398, or 1-pentyl-3-(4-chloro-1-naphthoyl)indole;
b. Any compound structurally derived from 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted in the naphthyl ring to any extent;
c. Any compound structurally derived from 1-(1-naphthylmethyl)indene by substitution at the 3-position of the indene ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indene ring to any extent, whether or not substituted in the naphthyl ring to any extent;

d. Any compound structurally derived from 3-phenylacetylindole by substitution at the nitrogen atom of the indole ring with alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Including, but not limited to:

(i) JWH-201, or 1-pentyl-3-(4-methoxyphenylacetyl)indole;

(ii) JWH-203, or 1-pentyl-3-(2-chlorophenylacetyl)indole;

(iii) JWH-250, or 1-pentyl-3-(2-methoxyphenylacetyl)indole;

(iv) JWH-251, or 1-pentyl-3-(2-methylphenylacetyl)indole;

(v) RCS-8, or 1-(2-cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole;

e. Any compound structurally derived from 2-(3-hydroxycyclohexyl)phenol by substitution at the 5-position of the phenolic ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not substituted in the cyclohexyl ring to any extent. Including, but not limited to CP 47, 497 and homologues, or 2-[(1R,3S)-3-hydroxycyclohexyl]-5-(2-methyloctan-2-yl)phenol, where side chain n=5, and homologues where side chain n-4,6, or 7;

f. Any compound containing a 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl) ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Including, but not limited to:

(i) AM-694, or 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole;

(ii) RCS-4, or 1-pentyl-3-(4-methoxybenzoyl)indole (SR-19 and RCS-4);

g. CP 50,556-1, or [(6S,6aR,9R,10aR)-9-hydroxy-6-methyl-3-[(2R)-5-phenylpentan-2-yl] oxy-5,6,6a,7,8,9,10,10a-octahydrophenanthridin-1-yl] acetate;

h. HU-210, or (6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c] chromen-1-ol;

i. HU-211, or Dexanabinol,(6aS,10aS)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol;

j. Dimethylheptylpyran, or DMHP;

(6) Any material, compound, mixture or preparation containing any quantity of the following substances having a depressant effect on the central nervous system, including their salts, isomers and salts of isomers whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:

(a) Gamma-hydroxybutyric acid;

(b) Mecloqualone;

(c) Methaqualone;

(7) Any material, compound, mixture or preparation containing any quantity of the following substances having a stimulant effect on the central nervous system, including their salts, isomers and salts of isomers:

(a) Aminorex;

(b) N-benzylpiperazine;

(c) Cathinone;

(d) Fenethylline;

(e) 3-Fluoromethcathinone;

(f) 4-Fluoromethcathinone;

(g) Mephedrone, or 4-methylmethcathinone;

(h) Methcathinone;

(i) 4-methoxymethcathinone;

(j) (+,-)cis-4-methylaminorex ((+,-)cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);

(k) Methylenedioxypyrovalerone, MDPV, or 1-(1,3-Benzodioxol-5-yl)-2-(1-pyrrolidinyl)-1-pentanone;

(l) Methylone, or 3,4-Methylenedioxymethcathinone;

(m) 4-Methyl-alpha-pyrrolidinobutiophenone, or MPBP;

(n) N-ethylamphetamine;

(o) N,N-dimethylamphetamine;

(p) Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC);

(q) Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22);

(r) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA);

(s) N-(1-amino-3, 3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA);

(8) A temporary listing of substances subject to emergency scheduling under federal law shall include any material, compound, mixture or preparation which contains any quantity of the following substances:

(a) (1-pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone, its optical, positional, and geometric isomers, salts, and salts of isomers;

(b) [1-(5-fluoro-pentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone, its optical, positional, and geometric isomers, salts, and salts of isomers;

(c) N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers;
(d) 2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine, its optical, positional, and geometric isomers, salts, and salts of isomers;
(e) 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine, its optical, positional, and geometric isomers, salts, and salts of isomers;
(f) 2-(4-bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine, its optical, positional, and geometric isomers, salts, and salts of isomers;
(g) 4-methyl-N-ethylcathinone, its optical, positional, and geometric isomers, salts, and salts of isomers;
(h) 4-methyl-alpha-pyrrolidinopropiophenone, its optical, positional, and geometric isomers, salts, and salts of isomers;
(i) Alpha-pyrrolidinopentiophenone, its optical, positional, and geometric isomers, salts, and salts of isomers;
(j) Butylone, its optical, positional, and geometric isomers, salts, and salts of isomers;
(k) Pentedrone, its optical, positional, and geometric isomers, salts, and salts of isomers;
(l) Pentylone, its optical, positional, and geometric isomers, salts, and salts of isomers;
(m) Naphyrone, its optical, positional, and geometric isomers, salts, and salts of isomers;
(n) Alpha-pyrrolidinobutiophenone, its optical, positional, and geometric isomers, salts, and salts of isomers;
(o) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers;
(p) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers;
(q) [1-(5-fluoropentyl)-1H-indazole-3-yl](naphthalen-1-yl)methanone, its optical, positional, and geometric isomers, salts, and salts of isomers;
(r) N-[1-[2-hydroxy-2-(thiophen-2-yl) ethyl]piperidin-4-yl]-N-phenylpropionamide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers;
(s) N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide, its optical, positional, and geometric isomers, salts, and salts of isomers;
(t) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers;
(u) methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers;
(v) methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers;
(w) N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers;
(x) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers;
(y) methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers;
(z) methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers;
(aa) N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers;
(bb) methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers;
(cc) N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers;
(dd) N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers;
(ee) N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers;
(ff) N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers;
(gg) N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers;
(hh) N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers;
(ii) N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers;
(jj) Fentanyl-related substances, their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers. Fentanyl-related substance shall mean any substance not otherwise listed under another Drug Enforcement Administration

Controlled Substance Code Number, and for which no exemption or approval is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 355, that is structurally related to fentanyl by one or more of the following modifications:

a. Replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

b. Substitution in or on the phenethyl group with alkyl, alkenyl, alkoxyl, hydroxyl, halo, haloalkyl, amino or nitro groups;

c. Substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, amino or nitro groups;

d. Replacement of the aniline ring with any aromatic monocycle, whether or not further substituted in or on the aromatic monocycle; or

e. Replacement of the N-propionyl group by another acyl group;

(kk) Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate, its optical, positional, and geometric isomers, salts, and salts of isomers (NM2201; CBL2201);

(ll) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers (5F-AB-PINACA);

(mm) 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers (4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYLBINACA; CUMYL-4CN-BINACA; SGT-78);

(nn) methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers (MMB-CHMICA, AMB-CHMICA);

(oo) 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers (5F-CUMYL-P7AICA);

(pp) N-ethylpentylone, its optical, positional, and geometric isomers, salts, and salts of isomers (ephylone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one;

(qq) ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers (trivial name: 5F-EDMB-PINACA);

(rr) methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate, its optical, positional, and geometric isomers, salts, and salts of isomers (trivial name: 5F-MDMB-PICA);

(ss) N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers (trivial names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL));

(tt) 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers (trivial names: 5F-CUMYL-PINACA; SGT-25);

(uu) (1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl) methanone, its optical, positional, and geometric isomers, salts, and salts of isomers (trivial name: FUB-144);

(vv) N-ethylhexedrone, its optical, positional, and geometric isomers, salts, and salts of isomers (Other name: 2-(ethylamino)-1-phenylhexan-1-one);

(ww) alpha-pyrrolidinohexanophenone, its optical, positional, and geometric isomers, salts, and salts of isomers (Other names: α-PHP; alpha-pyrrolidinohexiophenone; 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one);

(xx) 4-methyl-alpha-ethylaminopentiophenone, its optical, positional, and geometric isomers, salts, and salts of isomers; (Other names: 4-MEAP; 2-(ethylamino)-1-(4-methylphenyl)pentan-1-one);

(yy) 4'-methyl-alpha-pyrrolidinohexiophenone, its optical, positional, and geometric isomers, salts, and salts of isomers (Other names: MPHP; 4'-methyl-alpha-pyrrolidinohexanophenone; 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one);

(zz) alpha-pyrrolidinoheptaphenone, its optical, positional, and geometric isomers, salts, and salts of isomers (Other names: PV8; 1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one);

(aaa) 4'-chloro-alpha-pyrrolidinovalerophenone, its optical, positional, and geometric isomers, salts, and salts of isomers (Other names: 4-chloro-α-PVP; 4'-chloro-alpha-pyrrolidinopentiophenone; 1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one);

(9) Khat, to include all parts of the plant presently classified botanically as catha edulis, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seed or extracts.

3. The department of health and senior services shall place a substance in Schedule II if it finds that:

(1) The substance has high potential for abuse;

(2) The substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and

(3) The abuse of the substance may lead to severe psychic or physical dependence.

4. The controlled substances listed in this subsection are included in Schedule II:

(1) Any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(a) Opium and opiate; and any salt, compound, derivative or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxegol, naloxone, and naltrexone, and their

respective salts, but including the following:

a. Raw opium;
b. Opium extracts;
c. Opium fluid;
d. Powdered opium;
e. Granulated opium;
f. Tincture of opium;
g. Codeine;
h. Dihydroetorphine;
i. Ethylmorphine;
j. Etorphine hydrochloride;
k. Hydrocodone;
l. Hydromorphone;
m. Metopon;
n. Morphine;
o. Oripavine;
p. Oxycodone;
q. Oxymorphone;
r. Thebaine;

(b) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in this subdivision, but not including the isoquinoline alkaloids of opium;

(c) Opium poppy and poppy straw;

(d) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including the following:

a. Decocainized coca leaves or extractions of coca leaves, which extractions do not contain cocaine or ecgonine; or
b. Ioflupane;

(e) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy);

(2) Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

(a) Alfentanil;
(b) Alphaprodine;
(c) Anileridine;
(d) Bezitramide;
(e) Bulk dextropropoxyphene;
(f) Carfentanil;
(g) Dihydrocodeine;
(h) Diphenoxylate;
(i) Fentanyl;
(j) Isomethadone;
(k) Levo-alphacetylmethadol;
(l) Levomethorphan;
(m) Levorphanol;
(n) Metazocine;
(o) Methadone;
(p) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenylbutane;
(q) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid;
(r) Pethidine (meperidine);
(s) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;
(t) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;
(u) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperdine-4-carboxylic acid;
(v) Phenazocine;
(w) Piminodine;
(x) Racemethorphan;
(y) Racemorphan;
(z) Remifentanil;
(aa) Sufentanil;
(bb) Tapentadol;

(cc) Thiafentanil;

(3) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(a) Amphetamine, its salts, optical isomers, and salts of its optical isomers;

(b) Lisdexamfetamine, its salts, isomers, and salts of its isomers;

(c) Methamphetamine, its salts, isomers, and salts of its isomers;

(d) Phenmetrazine and its salts;

(e) Methylphenidate;

(4) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) Amobarbital;

(b) Glutethimide;

(c) Pentobarbital;

(d) Phencyclidine;

(e) Secobarbital;

(5) Hallucinogenic substances:

(a) Any material or compound which contains any quantity of nabilone;

(b) Dronabinol [(-)-Δ-9-trans tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration;

(6) Any material, compound, mixture, or preparation which contains any quantity of the following substances:

(a) Immediate precursor to amphetamine and methamphetamine: Phenylacetone;

(b) Immediate precursors to phencyclidine (PCP):

a. 1-phenylcyclohexylamine;

b. 1-piperidinocyclohexanecarbonitrile (PCC);

(c) Immediate precursor to fentanyl: 4-anilino-N-phenethyl-4-piperidine (ANPP);

(7) Any material, compound, mixture, or preparation which contains any quantity of the following alkyl nitrites:

(a) Amyl nitrite;

(b) Butyl nitrite.

5. The department of health and senior services shall place a substance in Schedule III if it finds that:

(1) The substance has a potential for abuse less than the substances listed in Schedules I and II;

(2) The substance has currently accepted medical use in treatment in the United States; and

(3) Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

6. The controlled substances listed in this subsection are included in Schedule III:

(1) Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:

(a) Benzphetamine;

(b) Chlorphentermine;

(c) Clortermine;

(d) Phendimetrazine;

(2) Any material, compound, mixture or preparation which contains any quantity or salt of the following substances or salts having a depressant effect on the central nervous system:

(a) Any material, compound, mixture or preparation which contains any quantity or salt of the following substances combined with one or more active medicinal ingredients:

a. Amobarbital;

b. Secobarbital;

c. Pentobarbital;

(b) Any suppository dosage form containing any quantity or salt of the following:

a. Amobarbital;

b. Secobarbital;

c. Pentobarbital;

(c) Any substance which contains any quantity of a derivative of barbituric acid or its salt;

(d) Chlorhexadol;

(e) Embutramide;

(f) Gamma hydroxybutyric acid and its salts, isomers, and salts of isomers contained in a drug product for which an application has been approved under Section 505 of the federal Food, Drug, and Cosmetic Act;

(g) Ketamine, its salts, isomers, and salts of isomers;

(h) Lysergic acid;

(i) Lysergic acid amide;

(j) Methyprylon;

(k) Perampanel, and its salts, isomers, and salts of isomers;
(l) Sulfondiethylmethane;
(m) Sulfonethylmethane;
(n) Sulfonmethane;
(o) Tiletamine and zolazepam or any salt thereof;

(3) Nalorphine;

(4) Any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs or their salts:

(a) Not more than 1.8 grams of codeine per one hundred milliliters or not more than ninety milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;
(b) Not more than 1.8 grams of codeine per one hundred milliliters or not more than ninety milligrams per dosage unit with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
(c) Not more than 1.8 grams of dihydrocodeine per one hundred milliliters or not more than ninety milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
(d) Not more than three hundred milligrams of ethylmorphine per one hundred milliliters or not more than fifteen milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;
(e) Not more than five hundred milligrams of opium per one hundred milliliters or per one hundred grams or not more than twenty-five milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts;
(f) Not more than fifty milligrams of morphine per one hundred milliliters or per one hundred grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(5) Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts: Buprenorphine;

(6) Anabolic steroids. Any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that promotes muscle growth, except an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for that administration. If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this subdivision. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation containing any quantity of the following substances, including its salts, esters and ethers:

(a) 3ß,17ß-dihydroxy-5*α*-androstane;
(b) 3*α*,17*β*-dihydroxy-5*α*-androstane;
(c) 5*α*-androstan-3,17-dione;
(d) 1-androstenediol (3*β*,17*β*-dihydroxy-5*α*-androst-1-ene);
(e) 1-androstenediol (3*α*,17*β*-dihydroxy-5*α*-androst-1-ene);
(f) 4-androstenediol (3*β*,17*β*-dihydroxy-androst-4-ene);
(g) 5-androstenediol (3*β*,17*β*-dihydroxy-androst-5-ene);
(h) 1-androstenedione ([5*α*]-androst-1-en-3,17-dione);
(i) 4-androstenedione (androst-4-en-3,17-dione);
(j) 5-androstenedione (androst-5-en-3,17-dione);
(k) Bolasterone (7*α*, 17*α*-dimethyl-17*β*-hydroxyandrost-4-en-3-one);
(l) Boldenone (17*β*-hydroxyandrost-1,4,-diene-3-one);
(m) Boldione;
(n) Calusterone (7*β*, 17*α*-dimethyl-17*β*-hydroxyandrost-4-en-3-one);
(o) Clostebol (4-chloro-17*β*-hydroxyandrost-4-en-3-one);
(p) Dehydrochloromethyltestosterone (4-chloro-17*β*-hydroxy-17*α*-methyl-androst-1,4-dien-3-one);
(q) Desoxymethyltestosterone;
(r) 4-dihydrotestosterone (17ß-hydroxy-androstan-3-one);
(s) Drostanolone (17ß-hydroxy-2*α*-methyl-5*α*-androstan-3-one);
(t) Ethylestrenol (17*α*-ethyl-17ß-hydroxyestr-4-ene);
(u) Fluoxymesterone (9-fluoro-17*α*-methyl-11ß,17ß-dihydroxyandrost-4-en-3-one);
(v) Formebolone (2-formyl-17*α*-methyl-11*α*,17ß-dihydroxyandrost-1,4-dien-3-one);
(w) Furazabol (17*α*-methyl-17ß-hydroxyandrostano[2,3-c]-furazan);
(x) 13ß-ethyl-17ß-hydroxygon-4-en-3-one;
(y) 4-hydroxytestosterone (4,17ß-dihydroxy-androst-4-en-3-one);
(z) 4-hydroxy-19-nortestosterone (4,17ß-dihydroxy-estr-4-en-3-one);
(aa) Mestanolone (17α-methyl-17ß-hydroxy-5α-androstan-3-one);
(bb) Mesterolone (1α- methyl-17ß-hydroxy-[5α]-androstan-3-one);
(cc) Methandienone (17α-methyl-17ß-hydroxyandrost-1,4-dien-3-one);

(dd) Methandriol (17α-methyl-3ß,17ß-dihydroxyandrost-5-ene);
(ee) Methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one);
(ff) Methenolone (1-methyl-17ß-hydroxy-5α-androst-1-en-3-one);
(gg) 17α-methyl-3β,17β-dihydroxy-5α-androstane;
(hh) 17α-methyl-3α,17β-dihydroxy-5α-androstane;
(ii) 17α-methyl-3β,17β-dihydroxyandrost-4-ene;
(jj) 17α-methyl-4-hydroxynandrolone (17α-methyl-4-hydroxy-17β-hydroxyestr-4-en-3-one);
(kk) Methyldienolone (17α-methyl-17β-hydroxyestra-4,9(10)-dien-3-one);
(ll) Methyltrienolone (17α-methyl-17β-hydroxyestra-4,9,11-trien-3-one);
(mm) Methyltestosterone (17α-methyl-17β-hydroxyandrost-4-en-3-one);
(nn) Mibolerone (7α,17α-dimethyl-17β-hydroxyestr-4-en-3-one);
(oo) 17α-methyl-Δ1-dihydrotestosterone (17β-hydroxy-17α-methyl-5α-androst-1-en-3-one) (a.k.a. '17-α-methyl-1-testosterone');
(pp) Nandrolone (17β-hydroxyestr-4-ene-3-one);
(qq) 19-nor-4-androstenediol (3β,17β-dihydroxyestr-4-ene);
(rr) 19-nor-4-androstenediol (3α,17β-dihydroxyestr-4-ene);
(ss) 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione);
(tt) 19-nor-5-androstenediol (3β,17β-dihydroxyestr-5-ene);
(uu) 19-nor-5-androstenediol (3α,17β-dihydroxyestr-5-ene);
(vv) 19-nor-4-androstenedione (estr-4-en-3,17-dione);
(ww) 19-nor-5-androstenedione (estr-5-en-3,17-dione);
(xx) Norbolethone (13β,17α-diethyl-17β-hydroxygon-4-en-3-one);
(yy) Norclostebol (4-chloro-17β-hydroxyestr-4-en-3-one);
(zz) Norethandrolone (17α-ethyl-17β-hydroxyestr-4-en-3-one);
(aaa) Normethandrolone (17α-methyl-17β-hydroxyestr-4-en-3-one);
(bbb) Oxandrolone (17α-methyl-17β-hydroxy-2-oxa-[5α]-androstan-3-one);
(ccc) Oxymesterone (17α-methyl-4,17β-dihydroxyandrost-4-en-3-one);
(ddd) metholone (17α-methyl-2-hydroxymethylene-17β-hydroxy-[5α]-androstan-3-one);
(eee) Prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole);
(fff) Stanolone (Δ1-dihydrotestosterone (a.k.a. 1-testosterone)(17β-hydroxy-5α-androst-1-en-3-one));
(ggg) Stanozolol (17α-methyl-17ß-hydroxy-[5α]-androst-2-eno[3,2-c]-pyrazole);
(hhh) Stenbolone (17ß-hydroxy-2-methyl-[5α]-androst-1-en-3-one);
(iii) Testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);
(jjj) Testosterone (17ß-hydroxyandrost-4-en-3-one);
(kkk) Tetrahydrogestrinone (13ß,17α-diethyl-17ß-hydroxygon-4,9,11-trien-3-one);
(lll) Trenbolone (17ß-hydroxyestr-4,9,11-trien-3-one);
(mmm) Any salt, ester, or ether of a drug or substance described or listed in this subdivision, except an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for that administration;

(7) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved drug product;

(8) The department of health and senior services may except by rule any compound, mixture, or preparation containing any stimulant or depressant substance listed in subdivisions (1) and (2) of this subsection from the application of all or any part of sections 195.010 to 195.320 if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system.

7. The department of health and senior services shall place a substance in Schedule IV if it finds that:

(1) The substance has a low potential for abuse relative to substances in Schedule III;

(2) The substance has currently accepted medical use in treatment in the United States; and

(3) Abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III.

8. The controlled substances listed in this subsection are included in Schedule IV:

(1) Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(a) Not more than one milligram of difenoxin and not less than twenty-five micrograms of atropine sulfate per dosage unit;

(b) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxybutane);

(c) 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers, and salts of these isomers (including tramadol);

(d) Any of the following limited quantities of narcotic drugs or their salts, which shall include one or more nonnarcotic

active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

a. Not more than two hundred milligrams of codeine per one hundred milliliters or per one hundred grams;

b. Not more than one hundred milligrams of dihydrocodeine per one hundred milliliters or per one hundred grams;

c. Not more than one hundred milligrams of ethylmorphine per one hundred milliliters or per one hundred grams;

(2) Any material, compound, mixture or preparation containing any quantity of the following substances, including their salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(a) Alfaxalone;
(b) Alprazolam;
(c) Barbital;
(d) Bromazepam;
(e) Camazepam;
(f) Carisoprodol;
(g) Chloral betaine;
(h) Chloral hydrate;
(i) Chlordiazepoxide;
(j) Clobazam;
(k) Clonazepam;
(l) Clorazepate;
(m) Clotiazepam;
(n) Cloxazolam;
(o) Delorazepam;
(p) Diazepam;
(q) Dichloralphenazone;
(r) Estazolam;
(s) Ethchlorvynol;
(t) Ethinamate;
(u) Ethyl loflazepate;
(v) Fludiazepam;
(w) Flunitrazepam;
(x) Flurazepam;
(y) Fospropofol;
(z) Halazepam;
(aa) Haloxazolam;
(bb) Ketazolam;
(cc) Loprazolam;
(dd) Lorazepam;
(ee) Lormetazepam;
(ff) Mebutamate;
(gg) Medazepam;
(hh) Meprobamate;
(ii) Methohexital;
(jj) Methylphenobarbital (mephobarbital);
(kk) Midazolam;
(ll) Nimetazepam;
(mm) Nitrazepam;
(nn) Nordiazepam;
(oo) Oxazepam;
(pp) Oxazolam;
(qq) Paraldehyde;
(rr) Petrichloral;
(ss) Phenobarbital;
(tt) Pinazepam;
(uu) Prazepam;
(vv) Quazepam;
(ww) Suvorexant;
(xx) Temazepam;
(yy) Tetrazepam;
(zz) Triazolam;

(aaa) Zaleplon;
(bbb) Zolpidem;
(ccc) Zopiclone;

(3) Any material, compound, mixture, or preparation which contains any quantity of the following substance including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible: fenfluramine;

(4) Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible: Lorcaserin;

(5) Any material, compound, mixture or preparation containing any quantity of the following substances having a stimulant effect on the central nervous system, including their salts, isomers and salts of isomers:

(a) Cathine ((+)-norpseudoephedrine);
(b) Diethylpropion;
(c) Fencamfamin;
(d) Fenproporex;
(e) Mazindol;
(f) Mefenorex;
(g) Modafinil;
(h) Pemoline, including organometallic complexes and chelates thereof;
(i) Phentermine;
(j) Pipradrol;
(k) Sibutramine;
(l) SPA ((-)-1-dimethyamino-1,2-diphenylethane);

(6) Any material, compound, mixture or preparation containing any quantity of the following substance, including its salts:

(a) Butorphanol (including its optical isomers);
(b) Eluxadoline (5-[[[(2S)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(1S)-1-(4-phenyl-1 H-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid) (including its optical isomers) and its salts, isomers, and salts of isomers;
(c) Pentazocine;

(7) Ephedrine, its salts, optical isomers and salts of optical isomers, when the substance is the only active medicinal ingredient;

(8) The department of health and senior services may except by rule any compound, mixture, or preparation containing any depressant substance listed in subdivision (1) of this subsection from the application of all or any part of sections 195.010 to 195.320 and sections 579.015 to 579.086 if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

9. The department of health and senior services shall place a substance in Schedule V if it finds that:

(1) The substance has low potential for abuse relative to the controlled substances listed in Schedule IV;

(2) The substance has currently accepted medical use in treatment in the United States; and

(3) The substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in Schedule IV.

10. The controlled substances listed in this subsection are included in Schedule V:

(1) Any compound, mixture or preparation containing any of the following narcotic drugs or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below, which also contains one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(a) Not more than two and five-tenths milligrams of diphenoxylate and not less than twenty-five micrograms of atropine sulfate per dosage unit;
(b) Not more than one hundred milligrams of opium per one hundred milliliters or per one hundred grams;
(c) Not more than five-tenths milligram of difenoxin and not less than twenty-five micrograms of atropine sulfate per dosage unit;

(2) Any material, compound, mixture or preparation which contains any quantity of the following substance having a stimulant effect on the central nervous system including its salts, isomers and salts of isomers: pyrovalerone;

(3) Any compound, mixture, or preparation containing any detectable quantity of pseudoephedrine or its salts or optical isomers, or salts of optical isomers or any compound, mixture, or preparation containing any detectable quantity of ephedrine or its salts or optical isomers, or salts of optical isomers;

(4) Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

(a) Brivaracetam ((25)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl]butanamide) (also referred to as BRV; UCB-34714; Briviact);
(b) Ezogabine [N-[2-amino-4(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester];
(c) Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide];
(d) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid];

(5) Any drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydro cannabinols.

11. If any compound, mixture, or preparation as specified in subdivision (3) of subsection 10 of this section is dispensed, sold, or distributed in a pharmacy without a prescription:

(1) All packages of any compound, mixture, or preparation containing any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers or ephedrine, its salts or optical isomers, or salts of optical isomers, shall be offered for sale only from behind a pharmacy counter where the public is not permitted, and only by a registered pharmacist or registered pharmacy technician; and

(2) Any person purchasing, receiving or otherwise acquiring any compound, mixture, or preparation containing any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers or ephedrine, its salts or optical isomers, or salts of optical isomers shall be at least eighteen years of age; and

(3) The pharmacist, intern pharmacist, or registered pharmacy technician shall require any person, prior to such person's purchasing, receiving or otherwise acquiring such compound, mixture, or preparation to furnish suitable photo identification that is issued by a state or the federal government or a document that, with respect to identification, is considered acceptable and showing the date of birth of the person;

(4) The seller shall deliver the product directly into the custody of the purchaser.

12. Pharmacists, intern pharmacists, and registered pharmacy technicians shall implement and maintain an electronic log of each transaction. Such log shall include the following information:

(1) The name, address, and signature of the purchaser;

(2) The amount of the compound, mixture, or preparation purchased;

(3) The date and time of each purchase; and

(4) The name or initials of the pharmacist, intern pharmacist, or registered pharmacy technician who dispensed the compound, mixture, or preparation to the purchaser.

13. Each pharmacy shall submit information regarding sales of any compound, mixture, or preparation as specified in subdivision (3) of subsection 10 of this section in accordance with transmission methods and frequency established by the department by regulation;

14. No person shall dispense, sell, purchase, receive, or otherwise acquire quantities greater than those specified in this chapter.

15. All persons who dispense or offer for sale pseudoephedrine and ephedrine products in a pharmacy shall ensure that all such products are located only behind a pharmacy counter where the public is not permitted.

16. The penalties for a knowing or reckless violation of the provisions of subsections 11 to 15 of this section are found in section 579.060.

17. The scheduling of substances specified in subdivision (3) of subsection 10 of this section and subsections 11, 12, 14, and 15 of this section shall not apply to any compounds, mixtures, or preparations that are in liquid or liquid-filled gel capsule form or to any compound, mixture, or preparation specified in subdivision (3) of subsection 10 of this section which must be dispensed, sold, or distributed in a pharmacy pursuant to a prescription.

18. The manufacturer of a drug product or another interested party may apply with the department of health and senior services for an exemption from this section. The department of health and senior services may grant an exemption by rule from this section if the department finds the drug product is not used in the illegal manufacture of methamphetamine or other controlled or dangerous substances. The department of health and senior services shall rely on reports from law enforcement and law enforcement evidentiary laboratories in determining if the proposed product can be used to manufacture illicit controlled substances.

19. The department of health and senior services shall revise and republish the schedules annually.

20. The department of health and senior services shall promulgate rules under chapter 536 regarding the security and storage of Schedule V controlled substances, as described in subdivision (3) of subsection 10 of this section, for distributors as registered by the department of health and senior services.

21. Logs of transactions required to be kept and maintained by this section and section 195.417 shall create a rebuttable presumption that the person whose name appears in the logs is the person whose transactions are recorded in the logs.

(L. 1971 H.B. 69, A.L. 1987 H.B. 51 & 49, A.L. 1989 S.B. 215 & 58, A.L. 1994 S.B. 594, A.L. 1996 H.B. 1301 & 1298, A.L. 1997 H.B. 635, A.L. 1998 H.B. 1357, A.L. 2001 H.B. 471, A.L. 2005 H.B. 353 merged with H.B. 441 merged with S.B. 10 & 27, A.L. 2006 S.B. 756, A.L. 2008 S.B. 724, A.L. 2010 H.B. 1472, A.L. 2011 H.B. 641, A.L. 2014 S.B. 491, A.L. 2018 H.B. 2034, A.L. 2020 H.B. 1896)

(1974) Held that classification of marijuana with more dangerous drugs is not violative of equal protection or due process. State v. Burrow (Mo.), 514 S.W.2d 585.

195.022. Chemical substances structurally similar to Schedule I controlled substances to be treated as Schedule I controlled substance.

Any analogue or homologue of a schedule I controlled substance shall be treated, for the purposes of any state law, as a controlled substance in schedule I.

(L. 1997 H.B. 635, A.L. 2011 H.B. 641)

195.030. Rules, procedure — fees — registration required, exceptions, registration, term not to exceed three years.

1. The department of health and senior services upon public notice and hearing pursuant to this section and chapter 536 may promulgate rules and charge reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances within this state. No rule or portion of a rule promulgated pursuant to the authority of this chapter shall become effective unless it has been promulgated pursuant to the provisions of section 536.024.

2. No person shall manufacture, compound, mix, cultivate, grow, or by any other process produce or prepare, distribute, dispense or prescribe any controlled substance and no person as a wholesaler shall supply the same, without having first obtained a registration issued by the department of health and senior services in accordance with rules and regulations promulgated by it. No registration shall be granted for a term exceeding three years.

3. Persons registered by the department of health and senior services pursuant to this chapter to manufacture, distribute, or dispense or conduct research with controlled substances are authorized to possess, manufacture, distribute or dispense such substances, including any such activity in the conduct of research, to the extent authorized by their registration and in conformity with other provisions of this chapter and chapter 579.

4. The following persons shall not be required to register and may lawfully possess controlled substances pursuant to this chapter and chapter 579:

(1) An agent or employee, excluding physicians, dentists, optometrists, podiatrists or veterinarians, of any registered manufacturer, distributor, or dispenser of any controlled substance if such agent is acting in the usual course of his or her business or employment;

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment;

(3) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a Schedule V substance.

5. The department of health and senior services may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if it finds it consistent with the public health and safety.

6. A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances.

7. The department of health and senior services is authorized to inspect the establishment of a registrant or applicant in accordance with the provisions of this chapter.

(RSMo 1939 § 9834, A.L. 1971 H.B. 69, A.L. 1989 S.B. 215 & 58, A.L. 1993 S.B. 52, A.L. 1995 S.B. 3, A.L. 1997 H.B. 635, A.L. 1999 H.B. 94 merged with S.B. 216, A.L. 2014 S.B. 491)
Effective 1-01-17

195.040. Registration requirements — revocation and suspension — review by administrative hearing commission — reapplication may be denied up to five years.

1. No registration shall be issued under section 195.030 unless and until the applicant therefor has furnished proof satisfactory to the department of health and senior services:

(1) That the applicant is of good moral character or, if the applicant be an association or corporation, that the managing officers are of good moral character;

(2) That the applicant is equipped as to land, buildings, and paraphernalia properly to carry on the business described in his or her application.

2. No registration shall be granted to any person who has within two years been finally adjudicated and found guilty, or entered a plea of guilty or nolo contendere, in a criminal prosecution under the laws of any state or of the United States, for any misdemeanor offense or within seven years for any felony offense related to controlled substances. No registration shall be granted to any person who is abusing controlled substances.

3. The department of health and senior services shall register an applicant to manufacture, distribute or dispense controlled substances unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

(2) Compliance with applicable state and local law;

(3) Any convictions of an applicant under any federal or state laws relating to any controlled substance;

(4) Past experience in the manufacture or distribution of controlled substances and the existence in the applicant's establishment of effective controls against diversion;

(5) Furnishing by the applicant of false or fraudulent material information in any application filed under this chapter;

(6) Suspension or revocation of the applicant's federal registration to manufacture, distribute or dispense narcotics or controlled dangerous drugs as authorized by federal law; and

(7) Any other factors relevant to and consistent with the public health and safety.

4. Registration does not entitle a registrant to manufacture and distribute controlled substances in Schedule I or II other than those specified in the registration.

5. Practitioners shall be registered to dispense any controlled substance or to conduct research with controlled substances in Schedules II through V if they are authorized to dispense or conduct research under the laws of this state. The department of health and senior services need not require separate registration under this chapter for practitioners engaging in research with nonnarcotic substances in Schedules II through V where the registrant is already registered under this chapter in another capacity. Practitioners registered under federal law to conduct research with Schedule I substances may conduct research with Schedule I substances within this state upon furnishing the department of health and senior services evidence of that federal registration.

6. Compliance by manufacturers and distributors with the provisions of federal law respecting registration, excluding fees, shall entitle them to be registered under this chapter.

7. A registration to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the department of health and senior services upon a finding that the registrant:

(1) Has furnished false or fraudulent material information in any application filed under this chapter;

(2) Has been convicted of a felony under any state or federal law relating to any controlled substance;

(3) Has had his or her federal registration to manufacture, distribute or dispense suspended or revoked;

(4) Has violated any federal controlled substances statute or regulation, or any provision of this chapter or chapter 579 or regulation promulgated under this chapter; or

(5) Has had the registrant's professional license to practice suspended or revoked.

8. The department of health and senior services may warn or censure a registrant; limit a registration to particular controlled substances or schedules of controlled substances; limit revocation or suspension of a registration to a particular controlled substance with respect to which grounds for revocation or suspension exist; restrict or limit a registration under such terms and conditions as the department of health and senior services considers appropriate for a period of five years; suspend or revoke a registration for a period not to exceed five years; or deny an application for registration. In any order of revocation, the department of health and senior services may provide that the registrant may not apply for a new registration for a period of time ranging from one to five years following the date of the order of revocation. All stay orders shall toll this time period. Any registration placed under a limitation or restriction by the department of health and senior services shall be termed "under probation".

9. If the department of health and senior services suspends or revokes a registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation order may be placed under seal by such agency and held pending final disposition of the case. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded, unless a court, upon application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances may be forfeited to the state.

10. The department of health and senior services may, upon review, terminate any restriction or limitation previously imposed upon a registration by the department of health and senior services if the registrant has remained in compliance with the imposed restrictions or limitations and local, state and federal laws since the time the restrictions or limitations were imposed.

11. The department of health and senior services shall promptly notify the Drug Enforcement Administration, United States Department of Justice, or its successor agency, of all orders suspending or revoking registration and all forfeitures of controlled substances.

12. If after first providing the registrant an opportunity for an informal conference, the department of health and senior services proposes to deny, suspend, restrict, limit or revoke a registration or refuse a renewal of registration, the department of health and senior services shall serve upon the applicant or registrant written notice of the proposed action to be taken on the application or registration. The notice shall contain a statement of the type of discipline proposed, the basis therefor, the date such action shall go into effect and a statement that the registrant shall have thirty days to request in writing a hearing before the administrative hearing commission. If no written request for a hearing is received by the department of health and senior services within thirty days of the applicant's or registrant's receipt of the notice, the proposed discipline shall take effect thirty-one days from the date the original notice was received by the applicant or registrant. If the registrant or applicant makes a written request for a hearing, the department of health and senior services shall file a complaint with the administrative hearing commission within sixty days of receipt of the written request for a hearing. The complaint shall comply with the laws and regulations for actions brought before the administrative hearing commission. The department of health and senior services may issue letters of censure or warning and may enter into agreements with a registrant or applicant which restrict or limit a registration without formal notice or hearing.

13. The department of health and senior services may suspend any registration simultaneously with the institution of proceedings under subsection 7 of this section if the department of health and senior services finds that there is imminent danger to the public health or safety which warrants this action. The suspension shall continue in effect until the conclusion of the

proceedings, including review thereof, unless sooner withdrawn by the department of health and senior services, dissolved by a court of competent jurisdiction or stayed by the administrative hearing commission.

(RSMo 1939 § 9835, A.L. 1971 H.B. 69, A.L. 1978 S.B. 651, A.L. 1987 H.B. 51 & 49, A.L. 1989 S.B. 215 & 58, A.L. 1994 S.B. 594, A.L. 1997 H.B. 635, A.L. 1998 H.B. 1147, et al., A.L. 2014 S.B. 491)
Effective 1-01-17

195.041. Emergencies, waiver of registration and record-keeping requirements for controlled substances, when.
In the event of an emergency as defined in section 44.010, the department of health and senior services may waive the registration and record-keeping requirements set forth in sections 195.010 to 195.100 and their attendant regulations if the department determines such a waiver would be in the best interest of the public health.

(L. 2002 S.B. 712)

195.042. Confidentiality of all complaints, investigatory reports and information, exceptions.
All complaints, investigatory reports, and information pertaining to any applicant, registrant or individual are confidential and shall only be disclosed upon written consent of the person whose records are involved or to other administrative or law enforcement agencies acting within the scope of their statutory authority. However, no applicant, registrant or individual shall have access to any complaints, investigatory reports or information concerning an investigation in progress until such time as the investigation has been completed. Information regarding identity, including names and addresses, registration, final disciplinary action taken and currency of the registration of the persons possessing registrations to conduct activities involving controlled substances and the names and addresses of the applicants shall not be confidential. This section shall not be construed to authorize the release of records, reports or other information which may be held in department files for any registrant or applicant which are subject to other specific state or federal laws concerning their disclosure.

(L. 1994 S.B. 594)

195.045. Civil immunity for persons required to report to the department of health and senior services.
Any person, organization, association or corporation who reports or provides information to the department of health and senior services pursuant to the provisions of this chapter and who does so in good faith shall not be subject to an action for civil damages as a result thereof.

(L. 1997 H.B. 635)

195.050. Controlled substances, legal sales, how made — records required to be kept.
1. A duly registered manufacturer or wholesaler may sell controlled substances to any of the following persons:
(1) To a manufacturer, wholesaler, or pharmacy;
(2) To a physician, dentist, podiatrist or veterinarian;
(3) To a person in charge of a hospital, but only for use in that hospital;
(4) To a person in charge of a laboratory, but only for use in that laboratory for scientific and medical purposes.
2. A duly registered manufacturer or wholesaler may sell controlled substances to any of the following persons:
(1) On a special written order accompanied by a certificate of exemption, as required by federal laws, to a person in the employ of the United States government or of any state, territorial, district, county, municipal or insular government, purchasing, receiving, possessing, or dispensing controlled substances by reason of his or her official duties;
(2) To a master of a ship or person in charge of any aircraft upon which no physician is regularly employed, for the actual medical needs of persons on board such ship or aircraft, when not in port; provided, such controlled substances shall be sold to the master of such ship or person in charge of such aircraft only in pursuance of a special order form approved by a commissioned medical officer or acting surgeon of the United States Public Health Service;
(3) To a person in a foreign country if the provisions of federal laws are complied with.
3. An official written order for any controlled substance listed in Schedules I and II shall be signed in duplicate by the person giving the order or by his or her duly authorized agent. The original shall be presented to the person who sells or dispenses the controlled substance named therein. In event of the acceptance of such order by the person, each party to the transaction shall preserve his or her copy of such order for a period of two years in such a way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this chapter or chapter 579. It shall be deemed a compliance with this subsection if the parties to the transaction have complied with federal laws, respecting the requirements governing the use of order forms.
4. Possession of or control of controlled substances obtained as authorized by this section shall be lawful if in the regular course of business, occupation, profession, employment, or duty of the possessor.
5. A person in charge of a hospital or of a laboratory, or in the employ of this state or of any other state, or of any political subdivision thereof, and a master or other proper officer of a ship or aircraft, who obtains controlled substances under the provisions of this section or otherwise, shall not administer, nor dispense, nor otherwise use such drugs, within this state, except within the scope of his or her employment or official duty, and then only for scientific or medicinal purposes and subject

to the provisions of this chapter and chapter 579.

6. Every person registered to manufacture, distribute or dispense controlled substances under this chapter shall keep records and inventories of all such drugs in conformance with the record keeping and inventory requirements of federal law, and in accordance with any additional regulations of the department of health and senior services.

7. Manufacturers and wholesalers shall keep records of all narcotic and controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared, and of all controlled substances received and disposed of by them, in accordance with this section.

8. Apothecaries shall keep records of all controlled substances received and disposed of by them, in accordance with the provisions of this section.

9. The form of records shall be prescribed by the department of health and senior services.

(RSMo 1939 § 9836, A.L. 1971 H.B. 69, A.L. 1989 S.B. 215 & 58, A.L. 2014 S.B. 491)
Effective 1-01-17

195.060. Controlled substances to be dispensed on prescription only, exception.

1. Except as provided in subsection 4 of this section, a pharmacist, in good faith, may sell and dispense controlled substances to any person only upon a prescription of a practitioner as authorized by statute, provided that the controlled substances listed in Schedule V may be sold without prescription in accordance with regulations of the department of health and senior services. All written prescriptions shall be signed by the person prescribing the same, except for electronic prescriptions. All prescriptions shall be dated on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is prescribed, and the full name, address, and the registry number under the federal controlled substances laws of the person prescribing, if he or she is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of the animal for which the drug is prescribed. The person filling the prescription shall either write the date of filling and his or her own signature on the prescription or retain the date of filling and the identity of the dispenser as electronic prescription information. The prescription or electronic prescription information shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of two years, so as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this law. No prescription for a drug in Schedule I or II shall be filled more than six months after the date prescribed; no prescription for a drug in Schedule I or II shall be refilled; no prescription for a drug in Schedule III or IV shall be filled or refilled more than six months after the date of the original prescription or be refilled more than five times unless renewed by the practitioner.

2. A pharmacist, in good faith, may sell and dispense controlled substances to any person upon a prescription of a practitioner located in another state, provided that the:

(1) Prescription was issued according to and in compliance with the applicable laws of that state and the United States; and

(2) Quantity limitations in subsection 4 of section 195.080 apply to prescriptions dispensed to patients located in this state.

3. The legal owner of any stock of controlled substances in a pharmacy, upon discontinuance of dealing in such drugs, may sell the stock to a manufacturer, wholesaler, or pharmacist, but only on an official written order.

4. A pharmacist, in good faith, may sell and dispense any Schedule II drug or drugs to any person in emergency situations as defined by rule of the department of health and senior services upon an oral prescription by an authorized practitioner.

5. Except where a bona fide physician-patient-pharmacist relationship exists, prescriptions for narcotics or hallucinogenic drugs shall not be delivered to or for an ultimate user or agent by mail or other common carrier.

(RSMo 1939 § 9837, A.L. 1957 p. 679, A.L. 1971 H.B. 69, A.L. 1989 S.B. 215 & 58, A.L. 1997 H.B. 635, A.L. 1998 H.B. 1147, et al., A.L. 2005 S.B. 74 & 49, A.L. 2010 H.B. 1965, A.L. 2012 H.B. 1563, A.L. 2014 S.B. 491, A.L. 2019 S.B. 514)

195.070. Prescriptive authority.

1. A physician, podiatrist, dentist, a registered optometrist certified to administer pharmaceutical agents as provided in section 336.220, or an assistant physician in accordance with section 334.037 or a physician assistant in accordance with section 334.747 in good faith and in the course of his or her professional practice only, may prescribe, administer, and dispense controlled substances or he or she may cause the same to be administered or dispensed by an individual as authorized by statute.

2. An advanced practice registered nurse, as defined in section 335.016, but not a certified registered nurse anesthetist as defined in subdivision (8) of section 335.016, who holds a certificate of controlled substance prescriptive authority from the board of nursing under section 335.019 and who is delegated the authority to prescribe controlled substances under a collaborative practice arrangement under section 334.104 may prescribe any controlled substances listed in Schedules III, IV, and V of section 195.017, and may have restricted authority in Schedule II. Prescriptions for Schedule II medications prescribed by an advanced practice registered nurse who has a certificate of controlled substance prescriptive authority are restricted to only those medications containing hydrocodone and Schedule II controlled substances for hospice patients pursuant to the provisions of section 334.104. However, no such certified advanced practice registered nurse shall prescribe controlled substance for his or her own self or family. Schedule III narcotic controlled substance and Schedule II - hydrocodone prescriptions shall be limited to a one hundred twenty-hour supply without refill.

3. A veterinarian, in good faith and in the course of the veterinarian's professional practice only, and not for use by a human

being, may prescribe, administer, and dispense controlled substances and the veterinarian may cause them to be administered by an assistant or orderly under his or her direction and supervision.

4. A practitioner shall not accept any portion of a controlled substance unused by a patient, for any reason, if such practitioner did not originally dispense the drug, except:

(1) When the controlled substance is delivered to the practitioner to administer to the patient for whom the medication is prescribed as authorized by federal law. Practitioners shall maintain records and secure the medication as required by this chapter and regulations promulgated pursuant to this chapter; or

(2) As provided in section 195.265.

5. An individual practitioner shall not prescribe or dispense a controlled substance for such practitioner's personal use except in a medical emergency.

(RSMo 1939 § 9838, A.L. 1971 H.B. 69, A.L. 1988 H.B. 1242 Revision, A.L. 1993 H.B. 564, A.L. 1997 H.B. 635, A.L. 2001 H.B. 471, A.L. 2008 S.B. 724, A.L. 2009 S.B. 296, A.L. 2014 S.B. 716 merged with S.B. 754, A.L. 2015 H.B. 709, A.L. 2018 S.B. 718 merged with S.B. 826 merged with S.B. 951, A.L. 2020 H.B. 1682, A.L. 2023 H.B. 115 & 99 merged with H.B. 402 merged with S.B. 70 merged with S.B. 157)

195.080. Excepted substances — prescription or dispensing limitation on amount of supply, exception — may be increased by physician, procedure.

1. Except as otherwise provided in this chapter and chapter 579, this chapter and chapter 579 shall not apply to the following cases: prescribing, administering, dispensing or selling at retail of liniments, ointments, and other preparations that are susceptible of external use only and that contain controlled substances in such combinations of drugs as to prevent the drugs from being readily extracted from such liniments, ointments, or preparations, except that this chapter and chapter 579 shall apply to all liniments, ointments, and other preparations that contain coca leaves in any quantity or combination.

2. Unless otherwise provided in sections 334.037, 334.104, and 334.747, a practitioner, other than a veterinarian, shall not issue an initial prescription for more than a seven-day supply of any opioid controlled substance upon the initial consultation and treatment of a patient for acute pain. Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill, or new prescription in compliance with the general provisions of this chapter and chapter 579. Prior to issuing an initial prescription for an opioid controlled substance, a practitioner shall consult with the patient regarding the quantity of the opioid and the patient's option to fill the prescription in a lesser quantity and shall inform the patient of the risks associated with the opioid prescribed. If, in the professional medical judgment of the practitioner, more than a seven-day supply is required to treat the patient's acute pain, the practitioner may issue a prescription for the quantity needed to treat the patient; provided, that the practitioner shall document in the patient's medical record the condition triggering the necessity for more than a seven-day supply and that a nonopioid alternative was not appropriate to address the patient's condition. The provisions of this subsection shall not apply to prescriptions for opioid controlled substances for a patient who is currently undergoing treatment for cancer or sickle cell disease, is receiving hospice care from a hospice certified under chapter 197 or palliative care, is a resident of a long-term care facility licensed under chapter 198, or is receiving treatment for substance abuse or opioid dependence.

3. A pharmacist or pharmacy shall not be subject to disciplinary action or other civil or criminal liability for dispensing or refusing to dispense medication in good faith pursuant to an otherwise valid prescription that exceeds the prescribing limits established by subsection 2 of this section.

4. Unless otherwise provided in this section, the quantity of Schedule II controlled substances prescribed or dispensed at any one time shall be limited to a thirty-day supply. The quantity of Schedule III, IV or V controlled substances prescribed or dispensed at any one time shall be limited to a ninety-day supply and shall be prescribed and dispensed in compliance with the general provisions of this chapter and chapter 579. The supply limitations provided in this subsection may be increased up to three months if the physician describes on the prescription form or indicates via telephone, fax, or electronic communication to the pharmacy to be entered on or attached to the prescription form the medical reason for requiring the larger supply. The supply limitations provided in this subsection shall not apply if:

(1) The prescription is issued by a practitioner located in another state according to and in compliance with the applicable laws of that state and the United States and dispensed to a patient located in another state; or

(2) The prescription is dispensed directly to a member of the United States Armed Forces serving outside the United States.

5. The partial filling of a prescription for a Schedule II substance is permissible as defined by regulation by the department of health and senior services.

(RSMo 1939 § 9839, A.L. 1965 p. 326, A.L. 1971 H.B. 69, A.L. 1987 H.B. 51 & 49, A.L. 1989 S.B. 215 & 58, A.L. 1997 H.B. 635, A.L. 2005 S.B. 74 & 49, A.L. 2010 S.B. 754, A.L. 2012 H.B. 1563, A.L. 2014 S.B. 491, A.L. 2018 S.B. 826, A.L. 2019 S.B. 514)

195.100. Labeling requirements.

1. It shall be unlawful to distribute any controlled substance in a commercial container unless such container bears a label containing an identifying symbol for such substance in accordance with federal laws.

2. It shall be unlawful for any manufacturer of any controlled substance to distribute such substance unless the labeling

thereof conforms to the requirements of federal law and contains the identifying symbol required in subsection 1 of this section.

3. The label of a controlled substance in Schedule II, III or IV shall, when dispensed to or for a patient, contain a clear, concise warning that it is a criminal offense to transfer such narcotic or dangerous drug to any person other than the patient.

4. Whenever a manufacturer sells or dispenses a controlled substance and whenever a wholesaler sells or dispenses a controlled substance in a package prepared by him or her, the manufacturer or wholesaler shall securely affix to each package in which that drug is contained a label showing in legible English the name and address of the vendor and the quantity, kind, and form of controlled substance contained therein. No person except a pharmacist for the purpose of filling a prescription under this chapter, shall alter, deface, or remove any label so affixed.

5. Whenever a pharmacist or practitioner sells or dispenses any controlled substance on a prescription issued by a physician, physician assistant, dentist, podiatrist, veterinarian, or advanced practice registered nurse, the pharmacist or practitioner shall affix to the container in which such drug is sold or dispensed a label showing his or her own name and address of the pharmacy or practitioner for whom he or she is lawfully acting; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the physician, physician assistant, dentist, podiatrist, advanced practice registered nurse, or veterinarian by whom the prescription was written; and such directions as may be stated on the prescription. No person shall alter, deface, or remove any label so affixed.

(RSMo 1939 § 9841, A.L. 1971 H.B. 69, A.L. 1989 S.B. 215 & 58, A.L. 1997 H.B. 635, A.L. 1998 H.B. 1147, et al., A.L. 2008 S.B. 724, A.L. 2009 S.B. 296, A.L. 2014 S.B. 491, A.L. 2019 S.B. 514, A.L. 2023 H.B. 402 merged with S.B. 70 merged with S.B. 157)

195.205. Immunity from liability for seeking or obtaining medical assistance for a drug overdose, when — law enforcement to provide information and resources, when.

1. For purposes of this section, the following terms shall mean:

(1) "Drug or alcohol overdose", a condition including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, mania, or death which is the result of consumption or use of a controlled substance or alcohol or a substance with which the controlled substance or alcohol was combined, or that a person would reasonably believe to be a drug or alcohol overdose that requires medical assistance;

(2) "Medical assistance", includes, but is not limited to, reporting a drug or alcohol overdose or other medical emergency to law enforcement, the 911 system, a poison control center, or a medical provider; assisting someone so reporting; or providing care to someone who is experiencing a drug or alcohol overdose or other medical emergency while awaiting the arrival of medical assistance.

2. A person who, in good faith, seeks or obtains medical assistance for someone who is experiencing a drug or alcohol overdose or other medical emergency or a person experiencing a drug or alcohol overdose or other medical emergency who seeks medical assistance for himself or herself or is the subject of a good faith request shall not be arrested, charged, prosecuted, convicted, or have his or her property subject to civil forfeiture or otherwise be penalized for the following if the evidence for the arrest, charge, prosecution, conviction, seizure, or penalty was gained as a result of seeking or obtaining medical assistance:

(1) Committing a prohibited act under section* 579.015, 579.074, 579.078, or 579.105;

(2) Committing a prohibited act under section* 311.310, 311.320, or 311.325;

(3) Violating a restraining order; or

(4) Violating probation or parole.

3. (1) This section shall not prohibit a police officer from arresting a person for an outstanding warrant under subsection 1 of section 221.510.

(2) This section shall not prohibit a person from being arrested, charged, or prosecuted based on an offense other than an offense under subsection 2 of this section, whether the offense arises from the same circumstances as the seeking of medical assistance.

(3) The protection of prosecution under this section for possession offenses shall not be grounds for suppression of evidence or dismissal in charges unrelated to this section.

4. Any police officer who is in contact with any person or persons in need of emergency medical assistance under this section shall provide appropriate information and resources for substance-related assistance.

(L. 2017 S.B. 501)

**Word "sections" appears in original rolls.*

(2021) Section was enacted as a new provision, and thus retroactive application was not barred to defendant under savings statute of section 1.160 in prosecution for unlawful possession of controlled substance or of drug paraphernalia.. State v. Vaughn, 2021 WL 6121847 (Mo.App.E.D.).

195.206. Opioid antagonist or addiction mitigation medicine, sale and dispensing of by pharmacists, possession of — administration of, contacting emergency personnel — immunity from liability, when.

1. As used in this section, the following terms shall mean:

(1) "Addiction mitigation medication", naltrexone hydrochloride that is administered in a manner approved by the United

States Food and Drug Administration or any accepted medical practice method of administering;

(2) "Opioid antagonist", naloxone hydrochloride, or any other drug or device approved by the United States Food and Drug Administration, that blocks the effects of an opioid overdose and is administered in a manner approved by the United States Food and Drug Administration or any accepted medical practice method of administering;

(3) "Opioid-related drug overdose", a condition including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma, or death resulting from the consumption or use of an opioid or other substance with which an opioid was combined or a condition that a layperson would reasonably believe to be an opioid-related drug overdose that requires medical assistance.

2. Notwithstanding any other law or regulation to the contrary:

(1) The director of the department of health and senior services, if a licensed physician, may issue a statewide standing order for an opioid antagonist or an addiction mitigation medication;

(2) In the alternative, the department may employ or contract with a licensed physician who may issue a statewide standing order for an opioid antagonist or an addiction mitigation medication with the express written consent of the department director.

3. Notwithstanding any other law or regulation to the contrary, any licensed pharmacist in Missouri may sell and dispense an opioid antagonist or an addiction mitigation medication under physician protocol or under a statewide standing order issued under subsection 2 of this section.

4. A licensed pharmacist who, acting in good faith and with reasonable care, sells or dispenses an opioid antagonist or an addiction mitigation medication and an appropriate device to administer the drug, and the protocol physician, shall not be subject to any criminal or civil liability or any professional disciplinary action for prescribing or dispensing the opioid antagonist or an addiction mitigation medication or any outcome resulting from the administration of the opioid antagonist or an addiction mitigation medication. A physician issuing a statewide standing order under subsection 2 of this section shall not be subject to any criminal or civil liability or any professional disciplinary action for issuing the standing order or for any outcome related to the order or the administration of the opioid antagonist or an addiction mitigation medication.

5. Notwithstanding any other law or regulation to the contrary, it shall be permissible for any person to possess an opioid antagonist or an addiction mitigation medication.

6. Any person who administers an opioid antagonist to another person shall, immediately after administering the drug, contact emergency personnel. Any person who, acting in good faith and with reasonable care, administers an opioid antagonist to another person whom the person believes to be suffering an opioid-related drug overdose shall be immune from criminal prosecution, disciplinary actions from his or her professional licensing board, and civil liability due to the administration of the opioid antagonist.

(L. 2016 H.B. 1568, A.L. 2017 S.B. 501, A.L. 2022 H.B. 2162 merged with H.B. 2331, A.L. 2023 S.B. 24 merged with S.B. 45 merged with S.B. 70 merged with S.B. 157 merged with S.B. 186)

195.265. Disposal of unused controlled substances, permitted methods — awareness program.

1. Unused controlled substances may be accepted from ultimate users, from hospice or home health care providers on behalf of ultimate users to the extent federal law allows, or from any person lawfully entitled to dispose of a decedent's property if the decedent was an ultimate user who died while in lawful possession of a controlled substance, through:

(1) Collection receptacles, drug disposal boxes, mail-back packages, and other means by a Drug Enforcement Agency-authorized collector in accordance with federal regulations, even if the authorized collector did not originally dispense the drug; or

(2) Drug take-back programs conducted by federal, state, tribal, or local law enforcement agencies in partnership with any person or entity.

This subsection shall supersede and preempt any local ordinances or regulations, including any ordinances or regulations enacted by any political subdivision of the state, regarding the disposal of unused controlled substances. For the purposes of this section, the term "ultimate user" shall mean a person who has lawfully obtained and possesses a controlled substance for his or her own use or for the use of a member of his or her household or for an animal owned by him or her or a member of his or her household.

2. By August 28, 2019, the department of health and senior services shall develop an education and awareness program regarding drug disposal, including controlled substances. The education and awareness program may include, but not be limited to:

(1) A web-based resource that:

(a) Describes available drug disposal options, including take back, take-back events, mail-back packages, in-home disposal options that render a product safe from misuse, or any other methods that comply with state and federal laws and regulations, may reduce the availability of unused controlled substances, and may minimize the potential environmental impact of drug disposal;

(b) Provides a list of drug disposal take-back sites, which may be sorted and searched by name or location and is updated every six months by the department;

(c) Provides a list of take-back events and mail-back events in the state, including the date, time, and location

information for each event and is updated every six months by the department; and

(d) Provides information for authorized collectors regarding state and federal requirements to comply with the provisions of subsection 1 of this section; and

(2) Promotional activities designed to ensure consumer awareness of proper storage and disposal of prescription drugs, including controlled substances.

(L. 2018 S.B. 718 merged with S.B. 826 merged with S.B. 951)
Effective 7-06-18 (S.B. 718); 7-06-18 (S.B. 826); 8-28-18 (S.B. 951)

195.400. Reports required, exceptions, penalties — person, defined — list of regulated chemicals.

1. As used in sections 195.400 to 195.425 the term "person" means any individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

2. Any manufacturer, wholesaler, retailer, or other person who sells, transfers, or otherwise furnishes any of the following substances to any person shall submit to the department of health and senior services a report, as prescribed by the department of health and senior services, of all such transactions:

(1) Anthranilic acid, its esters and its salts;
(2) Benzyl cyanide;
(3) Ergotamine and its salts;
(4) Ergonovine and its salts;
(5) N-Acetylanthranilic acid, its esters and its salts;
(6) Phenylacetic acid, its esters and its salts;
(7) Piperidine and its salts;
(8) 3,4,-Methylenedioxyphenyl-2-propanone;
(9) Acetic anhydride;
(10) Acetone;
(11) Benzyl Chloride;
(12) Ethyl ether;
(13) Hydriodic acid;
(14) Potassium permanganate;
(15) 2-Butanone (or Methyl Ethyl Ketone or MEK);
(16) Toluene;
(17) Ephedrine, its salts, optical isomers, and salts of optical isomers;
(18) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers;
(19) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers;
(20) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers;
(21) Methylamine and its salts;
(22) Ethylamine and its salts;
(23) Propionic anhydride;
(24) Isosafrole;
(25) Safrole;
(26) Piperonal;
(27) N-Methylephedrine, its salts, optical isomers and salts of optical isomers;
(28) N-Methylpseudoephedrine, its salts, optical isomers and salts of optical isomers;
(29) Benzaldehyde;
(30) Nitroethane;
(31) Methyl Isobutyl Ketone (MIBK);
(32) Sulfuric acid;
(33) Iodine;
(34) Red phosphorous;
(35) Gamma butyrolactone;
(36) 1,4 Butanediol.

3. The department of health and senior services by rule or regulation may add substances to or delete substances from subsection 2 of this section in the manner prescribed pursuant to section 195.017, if such substance is a component of or may be used to produce a controlled substance.

(L. 1989 S.B. 215 & 58, A.L. 1997 H.B. 635, A.L. 1998 H.B. 1147, et al., A.L. 2001 H.B. 471, A.L. 2010 H.B. 1965)

195.417. Limit on sale or dispensing of certain drugs, exceptions — prescription for certain substances not required, when, expiration when — local ordinances, state law to supercede and preempt — violations, penalty.

1. The limits specified in this section shall not apply to any quantity of such product, mixture, or preparation which must be dispensed, sold, or distributed in a pharmacy pursuant to a valid prescription.

2. Within any thirty-day period, no person shall sell, dispense, or otherwise provide to the same individual, and no person shall purchase, receive, or otherwise acquire more than the following amount: any number of packages of any drug product containing any detectable amount of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts or optical isomers, or salts of optical isomers, either as:

(1) The sole active ingredient; or

(2) One of the active ingredients of a combination drug; or

(3) A combination of any of the products specified in subdivisions (1) and (2) of this subsection;

in any total amount greater than seven and two-tenths grams, without regard to the number of transactions.

3. Within any twenty-four-hour period, no pharmacist, intern pharmacist, or registered pharmacy technician shall sell, dispense, or otherwise provide to the same individual, and no person shall purchase, receive, or otherwise acquire more than the following amount: any number of packages of any drug product containing any detectable amount of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts or optical isomers, or salts of optical isomers, either as:

(1) The sole active ingredient; or

(2) One of the active ingredients of a combination drug; or

(3) A combination of any of the products specified in subdivisions (1) and (2) of this subsection;

in any total amount greater than three and six-tenths grams without regard to the number of transactions.

4. Within any twelve-month period, no person shall sell, dispense, or otherwise provide to the same individual, and no person shall purchase, receive, or otherwise acquire more than the following amount: any number of packages of any drug product containing any detectable amount of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts or optical isomers, or salts of optical isomers, either as:

(1) The sole active ingredient; or

(2) One of the active ingredients of a combination drug; or

(3) A combination of any of the products specified in subdivisions (1) and (2) of this subsection;

in any total amount greater than forty-three and two-tenths grams, without regard to the number of transactions.

5. All packages of any compound, mixture, or preparation containing any detectable quantity of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts or optical isomers, or salts of optical isomers, except those that are excluded from Schedule V in subsection 17 or 18 of section 195.017, shall be offered for sale only from behind a pharmacy counter where the public is not permitted, and only by a registered pharmacist or registered pharmacy technician under section 195.017.

6. Each pharmacy shall submit information regarding sales of any compound, mixture, or preparation as specified in this section in accordance with transmission methods and frequency established by the department by regulation.

*7. No prescription shall be required for the dispensation, sale, or distribution of any drug product containing any detectable amount of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts or optical isomers, or salts of optical isomers, in an amount within the limits described in subsections 2, 3, and 4 of this section. The superintendent of the Missouri state highway patrol shall report to the revisor of statutes and the general assembly by February first when the statewide number of methamphetamine laboratory seizure incidents exceeds three hundred incidents in the previous calendar year. The provisions of this subsection shall expire on April first of the calendar year in which the revisor of statutes receives such notification.

8. This section shall supersede and preempt any local ordinances or regulations, including any ordinances or regulations enacted by any political subdivision of the state. This section shall not apply to the sale of any animal feed products containing ephedrine or any naturally occurring or herbal ephedra or extract of ephedra.

9. Any local ordinances or regulations enacted by any political subdivision of the state prior to August 28, 2020, requiring a prescription for the dispensation, sale, or distribution of any drug product containing any detectable amount of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts or optical isomers, or salts of optical isomers, in an amount within the limits described in subsections 2, 3, and 4 of this section shall be void and of no effect and no such political subdivision shall maintain or enforce such ordinance or regulation.

10. All logs, records, documents, and electronic information maintained for the dispensing of these products shall be open for inspection and copying by municipal, county, and state or federal law enforcement officers whose duty it is to enforce the controlled substances laws of this state or the United States.

11. All persons who dispense or offer for sale pseudoephedrine and ephedrine products, except those that are excluded from Schedule V in subsection 17 or 18 of section 195.017, shall ensure that all such products are located only behind a pharmacy counter where the public is not permitted.

12. The penalty for a knowing or reckless violation of this section is found in section 579.060.

(L. 2001 H.B. 471 merged with S.B. 89 & 37, A.L. 2003 H.B. 470 merged with S.B. 39, A.L. 2005 H.B. 441 merged with S.B. 10 & 27, A.L. 2008 S.B. 724, A.L. 2014 S.B. 491, A.L. 2020 H.B. 1682 merged with H.B. 1896)
**Contingent expiration date, subsection 7.*

195.418. Limitations on the retail sale of methamphetamine precursor drugs — violations, penalty.

1. The retail sale of methamphetamine precursor drugs shall be limited to:

(1) Sales in packages containing not more than a total of three grams of one or more methamphetamine precursor drugs, calculated in terms of ephedrine base, pseudoephedrine base and phenylpropanolamine base; and

(2) For nonliquid products, sales in blister packs, each blister containing not more than two dosage units, or where the use of blister packs is technically infeasible, sales in unit dose packets or pouches.

2. The penalty for a knowing violation of subsection 1 of this section is found in section 579.060.

(L. 2001 H.B. 471 merged with S.B. 89 & 37, A.L. 2014 S.B. 491)
Effective 1-01-17

195.550. Electronic prescriptions required, when, exceptions — violations.

1. Notwithstanding any other provision of this section or any other law to the contrary, beginning January 1, 2021, no person shall issue any prescription in this state for any Schedule II, III, or IV controlled substance unless the prescription is made by electronic prescription from the person issuing the prescription to a pharmacy, except for prescriptions:

(1) Issued by veterinarians;

(2) Issued in circumstances where electronic prescribing is not available due to temporary technological or electrical failure;

(3) Issued by a practitioner to be dispensed by a pharmacy located outside the state;

(4) Issued when the prescriber and dispenser are the same entity;

(5) Issued that include elements that are not supported by the most recently implemented version of the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard;

(6) Issued by a practitioner for a drug that the federal Food and Drug Administration requires the prescription to contain certain elements that are not able to be accomplished with electronic processing;

(7) Issued by a practitioner allowing for the dispensing of a nonpatient specific prescription pursuant to a standing order, approved protocol for drug therapy, collaborative drug management or comprehensive medication management, in response to a public health emergency, or other circumstances where the practitioner may issue a nonpatient specific prescription;

(8) Issued by a practitioner prescribing a drug under a research protocol;

(9) Issued by practitioners who have received an annual waiver, or a renewal thereof, from the requirement to use electronic prescribing, pursuant to a process established in regulation by the department of health and senior services, due to economic hardship, technological limitations, or other exceptional circumstances demonstrated by the practitioner;

(10) Issued by a practitioner under circumstances where, notwithstanding the practitioner's present ability to make an electronic prescription as required by this subsection, such practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition; or

(11) Issued where the patient specifically requests a written prescription.

2. A pharmacist who receives a written, oral, or faxed prescription is not required to verify that the prescription properly falls under one of the exceptions from the requirement to electronically prescribe. Pharmacists may continue to dispense medications from otherwise valid written, oral, or fax prescriptions that are consistent with state and federal laws and regulations.

3. An individual who violates the provisions of this section may be subject to discipline by his or her professional licensing board.

(L. 2019 S.B. 514)

195.600. Task force established — definitions — members, appointment, expenses — duties — controlled substance dispensation information, submitted to vendor, procedure — use of information — violation, penalty — rulemaking authority.

1. As used in this section, the following terms shall mean:

(1) "Controlled substance", as such term is defined in section 195.010;

(2) "Dispenser", a person who delivers a Schedule II, III, or IV controlled substance to a patient, but does not include:

(a) A hospital, as such term is defined in section 197.020, that distributes such substances for the purpose of inpatient care or dispenses prescriptions for controlled substances at the time of discharge from such facility;

(b) A practitioner or other authorized person who administers such a substance; or

(c) A wholesale distributor of a controlled substance;

(3) "Health care provider", as such term is defined in section 376.1350;

(4) "Patient", a person who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed, not including a hospice patient enrolled in a Medicare-certified hospice program who has controlled substances dispensed to him or her by such hospice program;

(5) "Schedule II, III, or IV controlled substance", a controlled substance that is listed in Schedule II, III, or IV of the schedules provided under this chapter or the Controlled Substances Act, 21 U.S.C. Section 812.

2. (1) There is hereby established within the office of administration the "Joint Oversight Task Force for Prescription Drug Monitoring", which shall be authorized to supervise the collection and use of patient dispensation information for prescribed Schedule II, III, or IV controlled substances as submitted by dispensers in this state under this section. The joint oversight

task force shall consist of the following members:

(a) Two members of the state board of registration for the healing arts who are licensed physicians or surgeons;

(b) Two members of the state board of pharmacy who are licensed pharmacists;

(c) One member of the state board of nursing who is an advanced practice registered nurse; and

(d) One member of the Missouri dental board who is a licensed dentist.

(2) The task force members shall be appointed by their respective state regulatory boards and shall serve a term not to exceed their term on such regulatory board, but in no case shall any term on the joint oversight task force exceed four years. Any member shall serve on the joint oversight task force until his or her successor is appointed. Any vacancy on the joint oversight task force shall be filled in the same manner as the original appointment. A chair of the joint oversight task force shall be selected by the members of the joint oversight task force.

(3) Members shall serve on the joint oversight task force without compensation, but may be reimbursed for their actual and necessary expenses from moneys appropriated to the office of administration. The office of administration shall provide technical, legal, and administrative support services as required by the joint oversight task force; provided, that the office of administration shall not have access to dispensation information or any other individually identifiable patient information submitted and retained under this section. The joint oversight task force shall be authorized to hire such staff as is necessary, subject to appropriations, to administer the provisions of this section.

(4) The joint oversight task force shall be considered a public body and shall be subject to the provisions of chapter 610.

3. (1) The joint oversight task force shall enter into a contract with a vendor, through a competitive bid process under chapter 34, for the operation of a program to monitor the dispensation of prescribed Schedules* II, III, and IV controlled substances. The vendor shall be responsible for the collection and maintenance of patient dispensation information submitted to the vendor by dispensers in this state and shall comply with the provisions of this section and the rules and regulations promulgated by the joint oversight task force.

(2) In addition to appropriations from the general assembly, the joint oversight task force may apply for available grants and shall be able to accept other gifts, grants, and donations to develop and maintain the program.

(3) The joint oversight task force shall be authorized to cooperate with the MO HealthNet division within the department of social services for the purposes of applying for and accepting any available federal moneys or other grants to develop and maintain the program; provided, that the joint oversight task force shall retain all authority over the program granted to it under this section and the MO HealthNet division shall not have access to the program or the information submitted to the program beyond such access as is granted to the division under this section.

4. Dispensation information submitted to the vendor under this section shall be as follows for each dispensation of a Schedule II, III, or IV controlled substance in this state:

(1) The pharmacy's Drug Enforcement Administration (DEA) number;

(2) The date of the dispensation;

(3) The following, if there is a prescription:

(a) The prescription number or other unique identifier;

(b) Whether the prescription is new or a refill; and

(c) The prescriber's DEA or National Provider Identifier (NPI) number;

(4) The National Drug Code (NDC) for the drug dispensed;

(5) The quantity and dosage of the drug dispensed;

(6) The patient's identification number including, but not limited to, any one of the following:

(a) The patient's driver's license number;

(b) The patient's government-issued identification number; or

(c) The patient's insurance cardholder identification number; and

(7) The patient's name, address, and date of birth.

The addition of any further information to the list of dispensation information required to be submitted in this subsection shall be the sole purview of the general assembly.

5. Each dispenser shall submit the information to the vendor electronically within twenty-four hours of dispensation. Beginning January 1, 2023, the vendor shall begin phasing in a requirement that dispensers report patient dispensation information in real time, with all dispensation information to be submitted in real time by January 1, 2024. The joint oversight task force may promulgate rules regarding alternative forms of transmission or waivers of the time frame established under this subsection due to unforeseen circumstances.

6. Beginning August 28, 2023, the vendor shall maintain an individual's dispensation information obtained under this section for a maximum of three years from the date of dispensation, after which such information shall be deleted from the program.

7. (1) The vendor shall treat patient dispensation information and any other individually identifiable patient information submitted under this section as protected health information under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), P.L. 104-191, and the regulations promulgated thereunder. Such information shall only be accessed and utilized in accordance with the privacy and security provisions of HIPAA and the provisions of this section.

(2) Dispensation information and any other individually identifiable patient information submitted under this section shall be confidential and not subject to public disclosure under chapter 610.

8. (1) The patient dispensation information submitted under this section shall only be utilized for the provision of health

care services to the patient. Prescribers, dispensers, and other health care providers shall be permitted to access a patient's dispensation information collected by the vendor in course of providing health care services to the patient. The vendor shall provide dispensation information to the individual patient, upon his or her request.

(2) The patient dispensation information submitted under this section shall be shared with any health information exchange operating in this state, upon the request of the health information exchange. Charges assessed to the health information exchange by the vendor shall not exceed the cost of the actual technology connection or recurring maintenance thereof. Any health information exchange receiving patient dispensation information under this subdivision shall comply with the provisions of subsection 7 of this section and such patient dispensation information shall only be utilized in accordance with the provisions of this section. For purposes of this subdivision, "health information exchange" means the electronic exchange of individually identifiable patient information among unaffiliated organizations according to nationally-recognized standards as administered by a health information organization, which shall not include an organized health care arrangement, as defined in 45 CFR 160.103, or a research institution that oversees and governs the electronic exchange of individually identifiable information among unaffiliated organizations for research purposes only.

9. The dispensation information of MO HealthNet program recipients submitted under this section may be shared with the MO HealthNet division for purposes of providing the division and MO HealthNet providers patient dispensation history and facilitating MO HealthNet claims processing and information retrieval; provided, that no patient dispensation information submitted under this section shall be utilized for any purpose prohibited under this section.

10. The joint oversight task force may provide data to public and private entities for statistical, research, or educational purposes only after removing information that could be used to identify individual patients, prescribers, dispensers, or persons who received dispensations from dispensers.

11. No patient dispensation information shall be provided to local, state, or federal law enforcement or prosecutorial officials, both in-state and out-of-state, or any regulatory board, professional or otherwise, for any purposes other than those explicitly set forth in HIPAA and any regulations promulgated thereunder.

12. No dispensation information submitted under this section shall be used by any local, state, or federal authority to prevent an individual from owning or obtaining a firearm.

13. No dispensation information submitted under this section shall be the basis for probable cause to obtain an arrest or search warrant as part of a criminal investigation.

14. (1) A dispenser who knowingly fails to submit dispensation information to the vendor as required under this section, or who knowingly submits incorrect dispensation information, shall be subject to an administrative penalty in the amount of one thousand dollars for each violation. The penalty shall be assessed through an order issued by the joint oversight task force. Any person subject to an administrative penalty may appeal to the administrative hearing commission under the provisions of chapter 621.

(2) Any person who unlawfully and purposefully accesses or discloses, or any person authorized to have patient dispensation information under this section who purposefully discloses, such information in violation of this section or purposefully uses such information in a manner and for a purpose in violation of this section is guilty of a class E felony.

15. (1) The provisions of this section shall supercede any local laws, ordinances, orders, rules, or regulations enacted by a county, municipality, or other political subdivision of this state for the purpose of monitoring the prescription or dispensation of prescribed controlled substances within the state. Any such prescription drug monitoring program in operation prior to August 28, 2021, shall cease operation within this state when the vendor's program under this section is available for utilization by prescribers and dispensers throughout the state.

(2) The joint oversight task force may enter into an agreement, or authorize the vendor to enter into an agreement, with any prescription drug monitoring program operated by a county, municipality, or other political subdivision of this state prior to August 28, 2021, to transfer patient dispensation information from the county, municipality, or other program to the vendor's program created under this section; provided, that such patient dispensation information shall be subject to the provisions of this section.

16. The provisions of this section shall not apply to persons licensed under chapter 340.

17. The joint oversight task force shall promulgate rules and regulations to implement the provisions of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2021, shall be invalid and void.

(L. 2021 S.B. 63 § 195.450)
**Word "Schedule" appears in original rolls.*

195.805. Edible marijuana — infused products, restrictions on design and shape — THC stamp required, when — violations, penalty — rulemaking authority.

1. No edible marijuana-infused product, packaging, or logo sold in Missouri pursuant to Article XIV of the Missouri Constitution shall be designed in the shape of a human, animal, or fruit, including realistic, artistic, caricature, or cartoon renderings.

However, geometric shapes, including, but not limited to, circles, squares, rectangles, and triangles, shall be permitted.

2. Each package, or packages with or within a package, containing an edible marijuana-infused product with ten or more milligrams of tetrahydrocannabinols (THC) shall be stamped with a universal symbol for such products, which shall consist of the following:

(1) A diamond containing the letters “THC”;

(2) The letter “M” located under the “THC” within the diamond, to signify that the product is for medical purposes; and

(3) The number of milligrams of THC in the package.

The universal symbol shall be placed on the front of the package in red and white print and shall measure one-half inch by one-half inch from point to point.

3. Any licensed or certified entity regulated by the department of health and senior services pursuant to Article XIV of the Missouri Constitution found to have violated the provisions of this section shall be subject to department sanctions, including an administrative penalty, in accordance with the regulations promulgated by the department pursuant to Article XIV of the Missouri Constitution.

4. The department shall promulgate rules and regulations prohibiting edible marijuana-infused products designed to appeal to persons under eighteen years of age, as well as promulgate rules and regulations to establish a process by which a licensed or certified entity may seek approval of an edible product design, package, or label prior to such product’s manufacture or sale in order to determine compliance with the provisions of this section and any rules promulgated pursuant to this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2020, shall be invalid and void.

(L. 2020 H.B. 1682 merged with H.B. 1896)

19 CSR 30-1
(BNDD Rules)

BNDD RULES

TITLE 19 — DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30 — Division of Regulation and Licensure
Chapter 1 — Controlled Substances

19 CSR 30-1.002 Schedules of Controlled Substances

PURPOSE: The Department of Health and Senior Services has prepared a list of all drugs falling within the purview of controlled substances.

(1) Schedules of Controlled Substances.

(A) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Drug Enforcement Administration (DEA) Controlled Substances Code Number set forth opposite it.

1. Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

A. Acetyl-alpha-methylfentanyl (N-(1-(1-methyl-2-phenethyl)-4-piperidinyl)-N-phenylacetamide) 9815
B. Acetylmethadol 9601
C. Acetyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide) 9821
D. N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers (other names: acryl fentanyl, acryloylfentanyl) 9811
E. AH-7921(3,4-dichloro-N-[(1-dimethylamino) cyclohexylmethyl] benzamide) 9551
F. Allylprodine 9602
G. Alphacetylmethadol (except levoalphacetylmethadol also known as levo-alpha-acetylmethadol levothadyl acetate or LAAM) 9603
H. Alphameprodine 9604
I. Alphamethadol 9605
J. Alpha-methylfentanyl (N-1-(alphamethyl-beta-phenyl) ethyl-4-piperidyl) propionanilide; 1-(1-methyl-2-phenylethyl)-4 ((N-propanilido) piperidine) 9814
K. Alpha-methylthiofentanyl (N-(1-methyl-2-(2-thienyl) ethyl-4-piperidinyl)-N-phenylpropanamide) 9832
L. Benzethidine 9606
M. Betacetylmethadol 9607
N. Beta-hydroxyfentanyl (N-(1-(2-hydroxy-2-phenethyl)-4-piperidinyl)-N-phenylpropanamide) 9830
O. Beta-hydroxy-3-methylfentanyl (other name: N-(1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl)-N-phenylpropanamide) 9831
P. N-[1-[2-hydroxy-2-(thiophen-2-yl) ethyl]piperidin-4-yl]-N-phenylpropionamide (other names: beta-hydroxythiofentanyl) 9836
Q. Betameprodine 9608
R. Betamethadol 9609
S. *beta*-Methyl fentanyl (N-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl) propionamide (Other name: β-methyl fentanyl) 9856
T. *beta*'-Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N,3-diphenylpropanamide (other names: β'-phenyl fentanyl; 3-phenylpropanoyl fentanyl) 9842
U. Betaprodine 9611
V. Clonitazene 9612
W. Crotonyl fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide) 9844
X. N-(1-phenethylpiperidin-4-yl)-N-Phenylcyclopentanecarboxamide (other name: cyclopentyl fentanyl) 9847
Y. Cyclopropyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide) 9845
Z. Dextromoramide 9613
AA. Diampromide 9615
BB. Diethylthiambutene 9616
CC. Difenoxin 9168
DD. Dimenoxadol 9617
EE. Dimepheptanol 9618
FF. Dimethylthiambutene 9619
GG. Dioxaphetyl butyrate 9621
HH. Dipipanone 9622
II. Ethylmethylthiambutene 9623
JJ. Etonitazene 9624
KK. Etoxeridine 9625
LL. Fentanyl carbamate (ethyl (1-phenethylpiperidin-4-yl) (phenyl)carbamate) 9851
MM. N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers (other names: 4-fluoroisobutyryl fentanyl, para-fluoroisobutyryl fentanyl) 9824

NN. 2'-Fluoro ortho-fluorofentanyl (N-(1-(2-fluorophenethyl) piperidin-4-yl)-N-(2-fluorophenyl) propionamide (other names: 2'-fluoro 2-fluorofentanyl) 9855
OO. N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide (other names: furanyl fentanyl) 9834
PP. Furethidine 9626
QQ. Hydroxypethidine 9627
RR. N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide (other name: isobutyryl fentanyl) 9827
SS. Isotonitazene (*N*,*N*-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl) ethan-1-amine) 9614
TT. Ketobemidone 9628
UU. Levomoramide 9629
VV. Levophenacylmorphan 9631
WW. Methoxyacetyl fentanyl (2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide 9825
XX. 4'-Methyl acetyl fentanyl (N-(1-(4-methylphenethyl) piperidin-4-yl)-N-phenylacetamide) 9819
YY. 3-Methylfentanyl (N-(3-methyl-1-(2-phenylethyl)-4-piperidyl)-N-phenylproanamide), its optical and geometric isomers, salts, and salts of isomers 9813
ZZ. 3-Methylthiofentanyl (N-(3-methyl-1-(2-thienyl)ethyl-4-piperidinyl)-N-phenylpropanamide) 9833
AAA. Morpheridine 9632
BBB. MPPP (1-methyl-4-phenyl-4-propionoxypiperidine) 9661
CCC. MT–45 (1-cyclohexyl-4-(1,2-diphenylethyl) piperazine) (9560)
DDD. Noracymethadol 9633
EEE. Norlevorphanol 9634
FFF. Normethadone 9635
GGG. Norpipanone 9636
HHH. *N*-(2-fluorophenyl)-2-methoxy-*N*-(1-phenethylpiperidin-4-yl)acetamide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers (other name: ocfentanil) 9838
III. *ortho*-Fluoroacryl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl) acrylamide) 9852
JJJ. *ortho*-Fluorobutyryl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl) butyramide (other name: 2-fluorobutyryl fentanyl) 9846
KKK. *ortho*-Fluorofentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl) propionamide); other name: 2-fluorofentanyl) 9816
LLL. *ortho*-Fluoroisobutyryl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide) 9853
MMM. *ortho*-Methyl acetylfentanyl (*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl) acetamide (other name: 2-methyl acetylfentanyl) 9848
NNN. *ortho*-Methyl methoxyacetyl fentanyl (2-methoxy-*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl) acetamide (other name: 2-methyl methoxyacetyl fentanyl) 9820
OOO. N-(4-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide (other name: para-chloroisobutyryl fentanyl) 9826
PPP. *para*-Fluorobutyryl fentanyl (*N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide) 9823
QQQ. *para*-fluorofentanyl(*N*-(4-fluorophenyl)-*N*-(1-(2-phenethyl)-4-piperidinyl) propanamide 9812
RRR. *para*-Fluoro furanyl fentanyl (*N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide) 9854
SSS. *para*-Methoxybutyryl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl) butyramide) 9837
TTT. *para*-Methylfentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl) propionamide (other name: 4-methylfentanyl) 9817
UUU. PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperidine) 9663
VVV. Phenadoxone 9637
WWW. Phenampromide 9638
XXX. Phenomorphan 9647

YYY. Phenoperidine 9641
ZZZ. Phenyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbenzamide (other name: benzoyl fentanyl) 9841
AAAA. Piritramide 9642
BBBB. Proheptazine 9643
CCCC. Properidine 9644
DDDD. Propiram 9649
EEEE. Racemoramide 9645
FFFF. *N*-(1-phenethylpiperidin-4-yl)-*N*-phenyltetrahydrofuran-2-carboxamide, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers (other name: tetrahydrofuranyl fentanyl) 9843
GGGG. Thiofentany (*N*-phenyl-*N*-(1-(2-thienyl)ethyl-4-piperidinyl)-propanamide 9835
HHHH. Thiofuranyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylthiophene-2-carboxamide (other names: 2-thiofuranyl fentanyl; thiophene fentanyl) 9839
IIII. Tilidine 9750
JJJJ. Trimeperidine 9646

2. Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

A. Acetorphine 9319
B. Acetyldihydrocodeine 9051
C. Benzylmorphine 9052
D. Codeine methylbromide 9070
E. Codeine-N-Oxide 9053
F. Cyprenorphine 9054
G. Desomorphine 9055
H. Dihydromorphine 9145
I. Drotebanol 9335
J. Etorphine (except hydrochloride salt) 9056
K. Heroin 9200
L. Hydromorphinol 9301
M. Methyldesorphine 9302
N. Methyldihydromorphine 9304
O. Morphine methylbromide 9305
P. Morphine methylsulfonate 9306
Q. Morphine-N-Oxide 9307
R. Myrophine 9308
S. Nicocodeine 9309
T. Nicomorphine 9312
U. Normorphine 9313
V. Pholcodine 9314
W. Thebacon 9315

3. Opiate Similar Synthetic Substances. Substances scheduled by the United States Drug Enforcement Administration as substances that share a pharmacological profile similar to fentanyl, morphine, and other synthetic opioids, unless specifically excepted or unless listed in another schedule. These substances are –

A. Butyryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutyramide) 9822
B. U–47700 (3,4-Dichloro-*N*-[2-(dimethylamino) cyclohexyl]-*N*-methylbenzamide) 9547
C. N-(1-phenethylpiperidin-4-yl)-*N*-phenylpentanamide (other name: valeryl fentanyl) 9840

4. Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation, which contains any quantity of the following hallucinogenic substances or which contains any of its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (For purposes of paragraph (1)(A)4. of this rule only, the term isomer includes the optical, position, and geometric isomers.):

A. Alpha-ethyltryptamine 7249
Some trade or other names: etryptamine; Monase; alpha-ethyl-1H-indole-3-ethenamine; 3-(2-aminobutyl)indole; alpha-ET; and AET;
B. 4-bromo-2,5-dimethoxyamphetamine 7391
Some trade or other names: 4-bromo-2, 5- dimethoxy-a-methylphenethylamine; 4-bromo- 2, 5-DMA;
C. 4-bromo-2,5-dimethoxyphenethylamine 7392
D. 2,5-dimethoxyamphetamine 7396
Some trade or other names: 2,5-dimethoxy-amethylphenethylamine; 2,5-DMA;
E. 2,5-dimethoxy-4-ethylamphetamine 7399
Some trade or other names: DOET;
F. 2,5-dimethoxy-4-(n)-propylthiophenethylamine (other name: 2C-T-7) 7348
G. 2-(2,5-Dimethoxy-4-(n)-propylphenyl) ethanamine (2C-P) 7524
H. 2-(2,5-Dimethoxy-4-ethylphenyl) ethanamine (2C-E) 7509
I. 2-(2,5-Dimethoxy-4-methylphenyl) ethanamine (2C-D) 7508
J. 2-(2,5-Dimethoxy-4-nitro-phenyl) ethanamine (2C-N) 7521
K. 2-(2,5-Dimethoxyphenyl) ethanamine (2C-H) 7517
L. 2-(4-Chloro-2,5-dimethoxyphenyl) ethanamine (2C-C) 7519
M. 2-(4-Ethylthio-2,5-dimethoxyphenyl) ethanamine (2C-T-2) 7385
N. 2-(4-Iodo-2,5-dimethoxyphenyl) ethanamine (2C-I) 7518
O. 2-(4-Isopropylthio)-2,5-dimethoxyphenyl) ethanamine (2C-T-4) 7532
P. 4-methoxyamphetamine 7411
Some trade or other names: 4-methoxy-amethylphenethylamine; paramethoxyamphetamine; PMA;
Q. 5-methoxy-3,4-methylenedioxyamphetamine 7401
R. 4-methyl-2,5-dimethoxyamphetamine 7395
Some trade and other names: 4-methyl-2, 5- dimethoxy-a-methylphenethylamine; DOM; and STP;
S. 3,4-methylenedioxyamphetamine 7400
T. 3,4-methylenedioxymetham-phetamine(MDMA) 7405
U. 3,4-methylenedioxy-*N*-ethylamphetamine (also known as *N*-ethylalpha-methyl-3,4 (methylenedioxy) phenethylamine, *N*-ethyl MDA, MDE, and MDEA) 7404

V. N-hydroxy-3,4-methylenedioxyamphetamine (also known as *N*-hydroxy-alpha-methyl-3,4 (methylenedioxy) phenethylamine and *N*-hydroxy MDA) 7402
W. 3,4,5-trimethoxyamphetamine 7390
X. 5-MeO-DMT or 5-methoxy-N,N-dimethyltryptamine 7431
Y. Alpha-methyltryptamine 7432
Z. Bufotenine 7433
Some trade and other names: 3-(b-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine;
AA. Diethyltryptamine 7434
Some trade and other names: N, N-Diethyltryptamine; DET;
BB. Dimethyltryptamine 7435
Some trade or other names: DMT;
CC. 5-methoxy-N,N-diisopropyltryptamine (other name: 5-MeODIPT) 7439
DD. Ibogaine 7260
Some trade and other names: 7-Ethyl- 6,6β,7,8,9,10,12,13-octahydro-2-methoxy-6, 9-methano-5H-pyrido [1',2':1,2] azepino[5,4-b] indole; Tabernanthe iboga;
EE. Lysergic acid diethylamide 7315
FF. Marihuana 7360
Some trade or other names: marijuana;
GG. Mescaline 7381
HH. Parahexyl 7374
Some trade or other names: 3-Hexyl-1- hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl- 6H-dibenzo[b,d]pyran; Synhexyl;
II. Peyote 7415
Meaning all parts of the plant presently classified botanically as Lophophora williamsii Lemaire, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or extracts;
JJ. N-ethyl-3-piperidyl benzilate 7482
KK. N-methyl-3-piperidyl benzilate 7484
LL. Psilocybin 7437
MM. Psilocyn 7438
NN. Tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (cannabis 7370 plant), as well as synthetic equivalents of the substances contained in the cannabis plant or in the resinous extractives of such plant, and/or synthetic substances, derivatives, and their isomers, or both, with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:
(I) 1 cis or trans tetrahydrocannabinol and their optical isomers;
(II) 6 cis or trans tetrahydrocannabinol and their optical isomers;
(III) 3,4 cis or trans tetrahydrocannabinol and its optical isomers; and
(IV) Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions are covered;
OO. Ethylamine analog of phencyclidine 7455
Some trade or other names: *N*-ethyl-1- phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, *N*-(1-phenylcyclohexyl)-ethylamine, cyclohexamine, PCE;
PP. Pyrrolidine analog of phencyclidine 7458
Some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine PCPy, PHP;
QQ. Thiophene analog of phencyclidine 7470
Some trade or other names: 1-(1-(2-thienyl)- cyclohexyl)-piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP;
RR. 1-(1-(2-thienyl)cyclohexyl) pyrrolidine 7473
Some other names: TCPy;
SS. Salvia divinorum
TT. Salvinorin A
UU. 3-Fluoromethcathinone 1233
VV. 4-Fluoromethcathinone 1238
WW. Mephedrone, or 4-methylmethcathinone 1248
XX. Methylenedioxy-pyrovalerone, MDPV, or (1-(1,3-Benzodioxol-5-yl)-2-(1-pyrrolidinyl)-1-pentanone 7535
YY. Methylone, or 3,4-Methylenedioxy-methcathinone 7540
ZZ. Quinolin-8-yl 1-pentyl-1Hindole-3-carboxylate (PB-22; QUPIC) 7222
AAA. Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22) 7225
BBB. *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1Hindazole-3-carboxamide (AB-FUBINACA) 7012
CCC. N-(1-amino-3, 3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA) 7035
DDD. (1-pentyl-1H-indol-3-yl) (2,2,3,3-tetramethylcyclopropyl) methanone (other names: UR-144, 1-pentyl-3-(2,2,3,3-tetramethylcyclopropoyl)indole) 7144
EEE. [1-(5-fluoro-pentyl)-1Hindol-3-yl](2,2,3,3-tetramethylcyclopropyl) methanone (other names: 5-fluoro-UR-144, 5-F-UR-144, XLR11, 1-(5-fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropoyl)indole) 7011
FFF. N-(1-adamantyl)-1-pentyl-1Hindazole-3-carboxamide (other names: APINACA, AKB48) 7048
GGG. 2-(4-iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (other names: 251-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5) 7538
HHH. 2-(4-chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (other names: 25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82) 7537

III. 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (other names: 25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36) 7536

JJJ. 4-methyl-N-ethylcathinone (other names: 4-MEC; 2-(ethylamino)-1-(4-methylphenyl)propan-1-one) 1249

KKK. 4-methyl-alphapyrrolidinopropiophenone, (other names: 4-MePPP; MePPP; 4-methyl-α-pyrrolidinopropiophenone; 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)-propan-1-one) 7498

LLL. *alpha*pyrrolidinopentiophenone (other names: α-PVP; α-pyrrolidinovalerophenone; 1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one) 7545

MMM. Butylone (other names: bk-MBDB; 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one) 7541

NNN. Pentedrone (other names: α-methylaminovalerophenone; 2-(methylamino)-1-phenylpentan-1-one) 1246

OOO. Pentylone (other names: bk-MBDP; 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one) 7542

PPP. Naphyrone (other names: naphthylpyrovalerone; 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one) 1258

QQQ. *alpha*-pyrrolidinobutiophenone (other names: α-PBP; 1-phenyl-2-(pyrrolidin-1-yl)butan-1-one) 7546

RRR. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (other names: AB-CHMINACA) 7031

SSS. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1Hindazole-3-carboxamide (other names: AB-PINACA) 7023

TTT. [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (other names: THJ-2201) 7024

UUU. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (other names: MAB-CHMINACA; ADB-CHMINACA) 7032

VVV. methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other names: 5F–ADB; 5F–MDMB–PINACA) 7034

WWW. methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (other names: 5F–AMB) 7033

XXX. N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other names: 5F–APINACA, 5F–AKB48) 7049

YYY. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other names: ADB–FUBINACA) 7010

ZZZ. methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other names: MDMB–CHMICA, MMB–CHMINACA) 7042

AAAA. methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other names: MDMB–FUBINACA) 7020

BBBB. methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (other names: FUB–AMB, MMB–FUBINACA, AMB–FUBINACA) (7021)

CCCC. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one (ethylone) 7547

DDDD. Naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (other names: NM2201; CBL2201) 7221

EEEE. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (other name: 5F-AB-PINACA) 7025

FFFF. 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (other names: 4-CN-CUMYLBUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYLBINACA; CUMYL-4CNBINACA; SGT-78) 7089

GGGG. methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate (other names: MMB-CHMICA; AMB-CHMICA) 7044

HHHH. 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-b]pyridine-3-carboxamide (other name: 5F-CUMYL-P7AICA) 7085

IIII. N-ethylpentylone (other names: ephylone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one) 7543
JJJJ. methyl 2-(1-(4-fluorobutyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (4F–MDMB–BINACA, 4F–MDMB–BUTINACA) 7043
KKKK. 1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: *para*-methoxymethamphetamine, PMMA) 1245
LLLL. ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-EDMB-PINACA) 7036
MMMM. methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-Dimethylbutanoate (other names: 5F-MDMB-PICA; 5F-MDMB-2201) 7041
NNNN. N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (other names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL)) 7047
OOOO. 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (other names: 5F-CUMYL-PINACA; SGT-25) 7083
PPPP. (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl) methanone (other name: FUB-144) 7014
QQQQ. *N*-Ethylhexedrone (other names: α-ethylaminohexanophenone; 2-(ethylamino)-1-phenylhexan-1-one) 7246
RRRR. *alpha*-Pyrrolidinohexanophenone (other names: α-PHP; α-pyrrolidinohexanophenone; 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one) 7544
SSSS. 4-Methyl-*alpha*-ethylaminopentiophenone (other names: 4-MEAP; 2-(ethylamino)-1-(4-methylphenyl)pentan-1-one) 7245
TTTT. 4′-Methyl-*alpha*-pyrrolidinohexiophenone (other names: MPHP; 4′-methyl-*alpha*-pyrrolidinohexanophenone; 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one) 7446
UUUU. *alpha*-Pyrrolidinoheptaphenone (other names: PV8; 1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one) 7548
VVVV. 4′-Chloro-*alpha*-pyrrolidinovalerophenone (other names: 4-chloro-α-PVP; 4′-chloro-α-pyrrolidinopentiophenone; 1-(4-chlorophenyl)-2-(pyrrolidin-1-yl) pentan-1-one) 7443
WWWW. 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine, MXE) 7286

XXXX. Synthetic cannabinoids: Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(I) Any compound structurally derived from 3-(1-naphthoyl)indole or 1Hindol-3-yl-(1-naphthyl)methane by substitution at the nitrogen atom of the indole ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent, whether or not substituted in the naphthyl ring to any extent. Including, but not limited to:

(a) AM2201, or 1-(5-fluoropentyl)-3-(1-naphthoyl)indole 7201
(b) JWH-007, or 1-pentyl-2-methyl-3-(1-naphthoyl)indole
(c) JWH-015, or 1-propyl-2-methyl-3-(1-naphthoyl)indole
(d) JWH-018, or 1-pentyl-3-(1-naphthoyl)indole 7118
(e) JWH-019, or 1-hexyl-3-(1-naphthoyl)indole 7019
(f) JWH-073, or 1-butyl-3-(1-naphthoyl)indole 7173
(g) JWH-081, or 1-pentyl-3-(4-methoxy-1-naphthoyl)indole 7081
(h) JWH-098, or 1-pentyl-2-methyl-3-(4-methoxy-1-naphthoyl)indole
(i) JWH-122, or 1-pentyl-3-(4-methyl-1-naphthoyl)indole 7122
(j) JWH-164, or 1-pentyl-3-(7-methoxy-1-naphthoyl)indole
(k) JWH-200, or 1-(2-(4-(morpholinyl)ethyl))-3-(1-naphthoyl)indole 7200
(l) JWH-210, or 1-pentyl-3-(4-ethyl-1-naphthoyl)indole
(m) JWH-398, or 1-pentyl-3-(4-chloro-1-naphthoyl)indole 7398

(II) Any compound structurally derived from 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(*N*-methyl-2- piperidinyl) methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted in the naphthyl ring to any extent;

(III) Any compound structurally derived from 1-(1-naphthylmethyl)indene by substitution at the 3-position of the indene ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(*N*-methyl-2- piperidinyl) methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indene ring to any extent, whether or not substituted in the naphthyl ring to any extent;

(IV) Any compound structurally derived from 3-phenylacetylindole by substitution at the nitrogen atom of the indole ring with alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(*N*-methyl-2- piperidinyl) methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent, whether or not substituted in the phenyl ring to any extent. Including, but not limited to:

(a) JWH-201, or 1-pentyl-3-(4-methoxyphenylacetyl)indole
(b) JWH-203, or 1-pentyl-3-(2-chlorophenylacetyl)indole 7203
(c) JWH-250, or 1-pentyl-3-(2-methoxypheny-lacetyl)indole 6250

(d) JWH-251, or 1-pentyl-3-(2-methylphenylacetyl)indole
(e) RCS-8, or 1-(2-cyclohexylethyl)-3-(2-methoxypheny-lacetyl)indole 7008

(V) Any compound structurally derived from 2-(3-hydroxycyclohexyl)phenol by substitution at the 5-position of the phenolic ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(*N*-methyl-2-piperidinyl) methyl or 2-(4-morpholinyl)ethyl group, whether or not substituted in the cyclohexyl ring to any extent. Including, but not limited to:

(a) CP 47,497 & homologues, or 2-[(1R,3S)-3-hydroxycyclohexyl]-5-(2-methyloctan-2-yl)phenol), where side chain n=5, and homologues where side chain n-4, 6, or 7 7297, 7298

(VI) Any compound containing a 3- (benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl or 2-(4-morpholinyl)ethyl group, whether or not further substituted in the indole ring to any extent and whether or not substituted in the phenyl ring to any extent. Including, but not limited to:

(a) AM-694, or 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole 7694
(b) RCS-4, or 1-pentyl-3-(4-methoxybenzoyl)indole (SR-19 and RCS-4) 7104

(VII) CP 50,556-1, or [(6S,6aR,9R,10aR)-9-hydroxy-6-methyl-3-[(2R)-5-phenylpentan-2-yl]oxy-5,6,6a,7,8,9,10,10a-octahydrophenanthridin- 1-yl] acetate;

(VIII) HU-210, or (6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c] chromen-1-ol;

(IX) HU-211, or Dexanabinol,(6aS,10aS)-9-(hydroxymethyl)- 6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol;

(X) Dimethylheptylpyran, or DMHP.

5. Depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

A. Gamma-hydroxybutyric acid and other names GHB; gamma-hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutonic acid; sodium oxybate; sodium oxybutryrate 2010
B. Mecloqualone 2572
C. Methaqualone 2565

6. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

A. Aminorex 1585
Some trade or other names: aminoxaphen; 2-amino-5-phenyl-2-oxazoline; 4,5-dihydro-5-phenyl-2-oxazolamine;
B. *N*-benzylpiperazine (some other names: BZP, 1-benzylpiperzaine) 7493
C. Cathinone (Some trade or other names: 2-amino-1-phenyl-1-propanone, alphaaminopropiophenone, 2-aminopropiophenone and norephedrone) 1235
D. 4,4′-Dimethylaminorex (4,4′-DMAR; 4,5-dihydro-4-methyl-5-(4-methylphenyl)-2-oxazolamine; 4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine) 1595
E. Fenethylline 1503
F. Methcathinone 1237
Some trade or other names: 2-(methylamino)-propiophenone; alpha-(methylamino) propiophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-*N*-methylaminopropiophenone; monomethylpropion; ephedrone; *N*-methylcathinone; methylcathinine; AL-464; AL-422; AL-463 and URI 432;
G. 4-methoxymethcathinone
H. cis-4-methylaminorex (cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine) 1590
I. 4-Methyl-alpha-pyrrolidinobutiophenone, or MPBP
J. N-ethylamphetamine 1475
K. N,N-dimethylamphetamine 1480
(some other names: *N*,*N*-alpha-trimethylbenzeneethanamine; *N*,*N*-alpha-trimethylphenethylamine)

7. A temporary listing of substances subject to emergency scheduling under federal law shall include any material, compound, mixture, or preparation which contains any quantity of the following substances:

A. Fentanyl-related substances, their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers. 9850

(I) Fentanyl-related substance means any substance not otherwise listed under another Administration Controlled Substance Code Number, and for which no exemption or approval is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act 21 U.S.C. 355, that is structurally related to fentanyl by one (1) or more of the following modifications:

(a) Replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

(b) Substitution in or on the phenethyl group with alkyl, alkenyl, alkoxyl, hydroxyl, halo, haloalkyl, amino, or nitro groups;

(c) Substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, halo, haloalkyl, amino, or nitro groups;

(d) Replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; and/or

(e) Replacement of the *N*-propionyl group by another acyl group.

B. 1-(1-(1-(4-bromophenyl) ethyl)piperidin-4-yl)-1, 3-dihydro-2*H*-benzo[*d*]imidazol-2-one, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers (Other names: brorphine; 1-[1-[1-(4-bromophenyl)ethyl]-4-piperidinyl]-1,3-dihydro-2H-benzimidazol-2-one) 9098

C. 2-(2-(4-butoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)-*N*, *N*-diethylethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (other name: Butonitazene) 9751

D. 2-(2-(4-ethoxybenzyl)-1*H*-benzimidazol-1-yl)-*N*, *N*-diethylethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (other names: Etodesnitazene; etazene) 9765

E. *N*, *N*-diethyl-2-(2-(4-fluorobenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (other name: Flunitazene) 9756

F. *N*,*N*-diethyl-2-(2-(4-methoxybenzyl)-1*H*-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (other name: Metodesnitazene) 9764

G. *N*, *N*-diethyl-2-(2-(4-methoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (other name: Metonitazene) 9757

H. 2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl) -1H-benzimidazole, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (other names: N-pyrrolidino etonitazene; etonitazepyne) 9758

I. *N*, *N*-diethyl-2-(5-nitro-2-(4-propoxybenzyl) -1*H*-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (other name: Protonitazene) 9759

8. Khat, to include all parts of the plant presently classified botanically as catha edulis, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seed, or extracts. 7032

(B) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

1. Substances, vegetable origin, or chemical synthesis. Unless specifically excepted or unless listed in another schedule, Schedule II shall include any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

A. Opium and opiate; and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxegol, naloxone, and naltrexone and their respective salts, but including the following:

(I) Raw opium 9600
(II) Opium extracts 9610
(III) Opium fluid 9620
(IV) Powdered opium 9639
(V) Granulated opium 9640
(VI) Tincture of opium 9630
(VII) Codeine 9050
(VIII) Dihydroetorphine 9334
(IX) Ethylmorphine 9190
(X) Etorphine hydrochloride 9059
(XI) Hydrocodone 9193
(XII) Hydromorphone 9150
(XIII) Metopon 9260
(XIV) Morphine 9300
(XV) Oripavine 9330
(XVI) Oxycodone 9143
(XVII) Oxymorphone 9652
(XVIII) Thebaine 9333

B. Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subparagraph (1)(B)1.A. of this rule shall be included in Schedule II, except that these substances shall not include the isoquinoline alkaloids of opium;

C. Opium poppy and poppy straw 9650

D. Coca leaves (9040) and any salt, compound, derivative, or preparation of coca leaves (including cocaine (9041) and ecgonine (9180) and their salts, isomers, derivatives, and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include:

(I) Decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine; or

(II) Ioflupane;

E. Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy) 9670

2. Opiates. Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan, and levopropoxyphene excepted:

A. Alfentanil 9737
B. Alphaprodine 9010
C. Anileridine 9020
D. Bezitramide 9800
E. Bulk Dextropropoxyphene (Non-dosage Forms) 9273
F. Carfentanil 9743
G. Dihydrocodeine 9120
H. Diphenoxylate 9170
I. Fentanyl 9801
J. Isomethadone 9226
K. Levo-alphacetylmethadol
Some other names: levo-alphaacetylmethadol, levomethadyl acetate, LAAM 9648
L. Levomethorphan 9210
M. Levorphanol 9220
N. Metazocine 9240
O. Methadone 9250
P. Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane 9254
Q. Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid 9802
R. Oliceridine (N-[(3-methoxythiophen-2-yl) methyl] ({2-[(9R)-9-(pyridin-2-yl)-6-oxaspiro [4.5]decan-9-yl]ethyl})amine fumarate) 9245
S. Pethidine (Meperidine) 9230

T. Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine 9232
U. Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate 9233
V. Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid 9234
W. Phenazocine 9715
X. Piminodine 9730
Y. Racemethorphan 9732
Z. Racemorphan 9733
AA. Remifentanil 9739
BB. Sufentanil 9740
CC. Tapentadol 9780
DD. Thiafentanil 9729

3. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

A. Amphetamine, its salts, optical isomers, and salts of its optical isomers 1100
B. Lisdexamfetamine, its salts, isomers, and salts of its isomers 1205
C. Methamphetamine, its salts, isomers, and salts of its isomers 1105
D. Phenmetrazine and its salts 1631
E. Methylphenidate 1724

4. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

A. Amobarbital 2125
B. Glutethimide 2550
C. Pentobarbital 2270
D. Phencyclidine 7471
E. Secobarbital 2315

5. Hallucinogenic substances:

A. Nabilone 7379

Another name for nabilone: (±)trans-3-(1, 1- dimethylheptyl)-6, 6a,7,8,10,10a-hexahydro- 1-hydroxy-6, 6-dimethyl-9H-dibenzo(b,d) pyran-9-one.

B. Dronabinol [(-)-delta-9-*trans* tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the United States Food and Drug Administration. (7365)

6. Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

A. Immediate precursor to amphetamine and methamphetamine:

(I) Phenylacetone 8501

Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone;

B. Immediate precursors to phencyclidine (PCP):

(I) 1-phenylcyclohexylamine 7460
(II) 1-piperidinocyclohexanecarbonitrile (PCC) 8603

C. Immediate precursor to fentanyl:

(I) 4-anilino-*N*-phenethyl-4-piperidine (ANPP) 8333
(II) *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl) 8366

7. Any material, compound, mixture, or preparation which contains any quantity of the following alkyl nitrites:

A. Amyl nitrite;
B. Butyl nitrite.

(C) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

1. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

A. Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under 21 CFR 308.32 and any other drug of the quantitive composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances 1405
B. Benzphetamine 1228
C. Chlorphentermine 1645
D. Clortermine 1647
E. Phendimetrazine 1615

2. Depressants. Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

A. Any compound, mixture, or preparation containing –
(I) Amobarbital 2126
(II) Secobarbital 2316
(III) Pentobarbital 2271

or any salt thereof and one (1) or more other active medicinal ingredients which are not listed in any schedule;

B. Any suppository dosage form containing –
(I) Amobarbital 2126
(II) Secobarbital 2316
(III) Pentobarbital 2271

or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository;

C. Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof 2100
D. Chlorhexadol 2510
E. Embutramide 2020
F. Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomer, for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act; 2012
G. Ketamine, its salts, isomer, and salts of isomers (some other names for ketamine: (±)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone) 7285
H. Lysergic acid 7300
I. Lysergic acid amide 7310
J. Methyprylon 2575
K. Perampanel, and its salts, isomers, and salts of isomers 2261

L. Sulfondiethylmethane 2600
M. Sulfonethylmethane 2605
N. Sulfonmethane 2610
O. Tiletamine and zolazepam or any salt thereof 7295

Some trade or other names for a tiletaminezolazepam combination product: Telazol.
Some trade or other names for tiletamine: 2- (ethylamino)-2-(2-thienyl)-cyclohexanone.
Some trade or other names for zolazepam: 4-(2-fluorophenyl)-6-8-dihydro-1,3,8- trimethylpyrazolo-(3,4-e) (1,4)-diazepin- 7(1H)-one, flupyrazapon.

3. Nalorphine 9400

4. Narcotics drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof:

A. Not more than one and eight tenths grams (1.8gm) of codeine per one hundred milliliters (100 mL) or not more than ninety milligrams (90 mg) per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium 9803

B. Not more than one and eight tenths grams (1.8gm) of codeine per one hundred milliliters (100 mL) or not more than ninety milligrams (90 mg) per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9804

C. Not more than one and eight tenths grams (1.8gm) of dihydrocodeine per one hundred milliliters (100 mL) or not more than ninety milligrams (90 mg) per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9807

D. Not more than three hundred milligrams (300 mg) of ethylmorphine per one hundred milliliters (100 mL) or not more than fifteen milligrams (15 mg) per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9808

E. Not more than five hundred milligrams (500 mg) of opium per one hundred milliliters (100 mL) or per one hundred grams (100 gm) or not more than twenty-five milligrams (25 mg) per dosage unit, with one (1) or more active nonnarcotic ingredients in recognized therapeutic amounts 9809

F. Not more than fifty milligrams (50 mg) of morphine per one hundred milliliters (100 mL) or per one hundred grams (100 gm), with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9810

5. Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts, as set forth below:

A. Buprenorphine 9064

6. Anabolic steroids. Unless specially excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation. DEA has assigned code 4000 for all anabolic steroids. Anabolic steroids. Any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that promotes muscle growth, except an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for that administration. If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this paragraph. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, esters, and ethers:

A. 3β,17β-dihydroxy-5α-androstane
B. 3α,17β-dihydroxy-5α-androstane
C. 5α-androstan-3,17-dione
D. 1-androstenediol (3β,17β-dihydroxy-5α-androst-1-ene)
E. 1-androstenediol (3α,17β-dihydroxy-5α-androst-1-ene)
F. 4-androstenediol (3β,17β-dihydroxy-androst-4-ene)
G. 5-androstenediol (3β,17β-dihydroxy-androst-5-ene)
H. 1-androstenedione ([5α]-androst-1-en-3,17-dione)
I. 4-androstenedione (androst-4-en-3,17-dione)
J. 5-androstenedione (androst-5-en-3,17-dione)
K. Bolasterone (7α,17α-dimethyl-17β-hydroxyandrost-4-en-3-one)
L. Boldenone (17β-hydroxyandrost-1, 4-diene-3-one)
M. Boldione (androstra-1,4-diene-3,17-dione)
N. Calusterone (7β,17α-dimethyl-17β-hydroxyandrost-4-en-3-one)
O. Clostebol (4-chloro-17β-hydroxyandrost-4-en-3-one)
P. Dehydrochloromethyltestosterone (4-chloro-17β-hydroxy-17α-methyl-androst-1, 4-dien-3-one)
Q. Desoxymethyltestosterone (17α-methyl-5α-androst-2-en-17β-ol) (a.k.a. madol)
R. Δ1-dihydrotestosterone (a.k.a.'1-testosterone')(17β-hydroxy-5α-androst-1-en-3-one)
S. 4-dihydrotestosterone (17β-hydroxy-androstan-3-one)
T. Drostanolone (17β-hydroxy-2α-methyl-5α-androstan-3-one)
U. Ethylestrenol (17α-ethyl-17β-hydroxyestr-4-ene)
V. Fluoxymesterone (9-fluoro-17α-methyl-11β,17β-dihydroxyandrost-4-en-3-one)
W. Formebulone (Formebolone) (2-formyl-17α-methyl-11α,17β-dihydroxyandrost-1,4-dien-3-one)
X. Furazabol (17α-methyl-17β-hydroxyandrostano[2,3-c]-furazan)
Y. 13β-ethyl-17β-hydroxygon-4-en-3-one
Z. 4-hydroxytestosterone (4,17β-dihydroxy-androst-4-en-3-one)
AA. 4-hydroxy-19-nortestosterone (4,17β-dihydroxy-estr-4-en-3-one)
BB. Mestanolone (17α-methyl-17β-hydroxy-5α-androstan-3-one)
CC. Mesterolone (1α-methyl-17β-hydroxy-[5α]-androstan-3-one)
DD. Methandienone (17α-methyl-17β-hydroxyandrost-1,4-dien-3-one)
EE. Methandriol (17α-methyl-3β,17β-dihydroxyandrost-5-ene)
FF. Methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one)
GG. Methenolone (1-methyl-17β-hydroxy-5α-androst-1-en-3-one)
HH. 17α-methyl-3β,17β-dihydroxy-5α-androstane
II. 17α-methyl-3α,17β-dihydroxy-5α-androstane
JJ. 17α-methyl-3β,17β-dihydroxyandrost-4-ene
KK. 17α-methyl-4-hydroxynandrolone(17α-methyl-4-hydroxy-17β-hydroxyestr-4-en-3-one)
LL. Methyldienolone (17α-methyl-17β-hydroxyestra-4,9(10)-dien-3-one)
MM. Methyltrienolone (17α-methyl-17β-hydroxyestra-4,9,11-trien-3-one)

NN. Methyltestosterone (17α-methyl-17-hydroxyandrost-4-en-3-one)

OO. Mibolerone (7α,17α-dimethyl-17β-hydroxyestr-4-en-3-one)

PP. 17α-methyl-Δ1-dihydrotestosterone (17β-hydroxy-17α-methyl-5α-androst-1-en-3-one) (a.k.a. 17-α-methyl-1-testosterone)

QQ. Nandrolone (17β-hydroxyestr-4-ene-3-one)

RR. 19-nor-4-androstenediol (3β,17β-dihydroxyestr-4-ene)

SS. 19-nor-4-andro stenediol (3α,17β-dihydroxyestr-4-ene)

TT. 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione)

UU. 19-nor-5-androstenediol (3β,17β-dihydroxyestr-5-ene)

VV. 19-nor-5-androstenediol (3α,17β-dihydroxyestr-5-ene)

WW. 19-nor-4-androstenedione (estr-4-en-3,17-dione)

XX. 19-nor-5-androstenedione (estr-5-en-3,17-dione)

YY. Norbolethone (13β,17α-diethyl-17β-hydroxygon-4-en-3-one)

ZZ. Norclostebol (4-chloro-17β-hydroxyestr-4-en-3-one)

AAA. Norethandrolone (17α-ethyl-17β-hydroxyestr-4-en-3-one)

BBB. Normethandrolone (17α-methyl-17β-hydroxyestr-4-en-3-one)

CCC. Oxandrolone (17α-methyl-17β-hydroxy-2-oxa-[5α]-androstan-3-one)

DDD. Oxymesterone (17α-methyl-4,17β-dihydroxyandrost-4-en-3-one)

EEE. Oxymetholone (17α-methyl-2-hydroxymethylene-17β-hydroxy-[5α]-androstan-3-one)

FFF. Prostanozol (17β-hydroxy-5α-androstano[3,2-c] pyrazole)

GGG. Stanolone (Δ1-dihydrotestosterone (a.k.a. 1-testosterone)(17β-hydroxy-5α-androst-1-en-3-one))

HHH. Stanozolol (17α-methyl-17β-hydroxy-[5α]-androst-2-eno[3,2-c]-pyrazole)

III. Stenbolone (17β-hydroxy-2-methyl-[5α]-androst-1-en-3-one)

JJJ. Testolactone(13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone)

KKK. Testosterone(17β-hydroxyandrost-4-en-3-one);

LLL. Tetrahydrogestrinone (13β,17α-diethyl-17β-hydroxygon-4,9, 11-trien-3-one)

MMM. Trenbolone (17β-hydroxyestr-4,9,11-trien-3-one)

NNN. Any salt, ester, or isomer of a drug or substance described or listed in this subparagraph, if that salt, ester, or isomer promotes muscle growth except an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for that administration.

7. Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved drug product 7369
(Some other names for dronabinol: (6aRtrans)- 6a,7,8,10a-tetrahydro-6.6.9-trimethyl-3-pentyl-6H-dibenzo (b,d) pyran-1-ol, or (-) -delta-9-(trans)-tetrahydrocannabinol.)

(D) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this subsection. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

1. Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof:

A. Not more than one milligram (1 mg) of difenoxin (DEA Drug Code No. 9168) and not less than twenty-five micrograms (25 mcg) of atropine sulfate per dosage unit 9167

B. Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane) 9278

C. 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl) cyclohexanol, its salts, optical and geometric isomers, and salts of these isomers (including tramadol) 9752

D. Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which shall include one (1) or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(I) Not more than two hundred milligrams (200 mg) of codeine per one hundred milliliters (100 mL) or per one hundred grams (100 gm);

(II) Not more than one hundred milligrams (100 mg) of dihydrocodeine per one hundred milliliters (100 mL) or per one hundred grams (100 gm); or

(III) Not more than one hundred milligrams (100 mg) of ethylmorphine per one hundred milliliters (100 mL) or per one hundred grams (100 gm).

2. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

A. Alfaxalone 2731
B. Alprazolam 2882
C. Barbital 2145
D. Brexanolone 2400
E. Bromazepam 2748
F. Camazepam 2749
G. Carisoprodol 8192
H. Chloral betaine 2460
I. Chloral hydrate 2465
J. Chlordiazepoxide 2744
K. Clobazam 2751
L. Clonazepam 2737
M. Clorazepate 2768
N. Clotiazepam 2752
O. Cloxazolam 2753
P. Daridorexant 2410
Q. Delorazepam 2754
R. Diazepam 2765
S. Dichloralphenazone 2467
T. Estazolam 2756
U. Ethchlorvynol 2540
V. Ethinamate 2545
W. Ethyl loflazepate 2758
X. Fludiazepam 2759
Y. Flunitrazepam 2763
Z. Flurazepam 2767
AA. Fospropofol 2138
BB. Halazepam 2762
CC. Haloxazolam 2771
DD. Ketazolam 2772
EE. Lemborexant 2245
FF. Loprazolam 2773

GG. Lorazepam 2885
HH. Lormetazepam 2774
II. Mebutamate 2800
JJ. Medazepam 2836
KK. Meprobamate 2820
LL. Methohexital 2264
MM. Methylphenobarbital (Mephobarbital) 2250
NN. Midazolam 2884
OO. Nimetazepam 2837
PP. Nitrazepam 2834
QQ. Nordiazepam 2838
RR. Oxazepam 2835
SS. Oxazolam 2839
TT. Paraldehyde 2585
UU. Petrichloral 2591
VV. Phenobarbital 2285
WW. Pinazepam 2883
XX. Prazepam 2764
YY. Quazepam 2881
ZZ. Remimazolam 2846
AAA. Suvorexant 2223
BBB. Temazepam 2925
CCC. Tetrazepam 2886
DDD. Triazolam 2887
EEE. Zaleplon 2781
FFF. Zolpidem 2783
GGG. Zopiclone 2784

3. Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

A. Fenfluramine 1670

4. Lorcaserin. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

A. Lorcaserin 1625

5. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

A. Cathine ((+)-norpseudoephedrine) 1230
B. Diethylpropion 1610
C. Fencamfamin 1760
D. Fenproporex 1575
E. Mazindol 1605
F. Mefenorex 1580
G. Modafinil 1680
H. Pemoline (including organometallic complexes and chelates thereof) 1530
I. Phentermine 1640
J. Pipradrol 1750
K. Serdexmethylphenidate 1729
L. Sibutramine 1675
M. Solriamfetol (2-amino-3-phenylpropyl carbamate; benzenepropanol, beta-amino-, carbamate (ester)) 1650
N. SPA (-)-1-dimethylamino-1,2-diphenylethane 1635

6. Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts:

A. Pentazocine 9709
B. Butorphanol (including its optical isomers) 9720
C. Eluxadoline (5-[[[(*2S*)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl] [(*1S*)-1-(4-phenyl-1 *H*-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid) (including its optical isomers) and its salts, isomers, and salts of isomers 9725

7. Ephedrine. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system including their salts, isomers, and salts of isomers:

A. Ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient.

(E) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this subsection.

1. Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as follows, which shall include one (1) or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

A. Not more than two hundred milligrams (200 mg) of codeine per one hundred milliliters (100 mL) or per one hundred grams (100 gm);

B. Not more than one hundred milligrams (100 mg) of dihydrocodeine per one hundred milliliters (100 mL) or per one hundred grams (100 gm);

C. Not more than one hundred milligrams (100 mg) of ethylmorphine per one hundred milliliters (100 mL) or per one hundred grams (100 gm);

D. Not more than two and five-tenths milligrams (2.5 mg) of diphenoxylate and not less than twenty-five micrograms (25 mcg) of atropine sulfate per dosage unit;

E. Not more than one hundred milligrams (100 mg) of opium per one hundred milliliters (100 mL) or per one hundred grams (100 gm); and

F. Not more than five-tenths milligram (0.5 mg) of difenoxin (DEA Drug Code No. 9168) and not less than twenty-five micrograms (25 mcg) of atropine sulfate per dosage unit.

2. Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system including its salts, isomers, and salts of isomers:

A. Pyrovalerone 1485

3. Any compound, mixture, or preparation containing any detectable quantity of pseudoephedrine or its salts or optical isomers, or salts of optical isomers or any compound, mixture, or preparation containing any detectable quantity of ephedrine or its salts or optical isomers, or salts of optical isomers if the drug preparations are starch-based solid dose forms, if such preparations are sold over the counter without a prescription. The following drug preparations containing ephedrine and pseudoephedrine are not scheduled controlled substances:

A. Drug preparations in liquid form; and

B. Drug preparations that require a prescription in order to be dispensed.

4. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

A. Ezogabine [N-[2-amino-4(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester]	2779
B. Ganaxolone (3α-hydroxy-3β-methyl-5α-pregnan-20-one)	2401
C. Lacosamide [(R)-2-acetoamido-*N*-benzyl-3-methoxy-propionamide]	2746
D. Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid]	2782
E. Brivaracetam ((25)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl]butanamide) (also referred to as BRV; UCB-34714; Briviact)	2710
F. Lasmiditan [2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl) pyridine-2-yl-benzamide]	2790
G. Cenobamate ([(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate; 2H-tetrazole-2-ethanol, alpha-(2-chlorophenyl)-, carbamate (ester), (alphaR)-; carbamic acid (R)-(+)-1-(2-chlorophenyl)-2-(2H-tetrazol-2-yl)ethyl ester)	2720

(2) Excluded Nonnarcotic Substances. The following nonnarcotic substances which, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) and section 201(g)(1) of the federal Controlled Substances Act (21 U.S.C. 811(g)(1)), may be lawfully sold over the counter without a prescription, are excluded from all schedules pursuant to section 195.015(5), RSMo.

Excluded Nonnarcotic Products

Company	Trade Name	NDC Code	Form	Controlled Substance	mg or mg/mL
Bioline Laboratories	Theophed	00719-1945	TB	Phenobarbital	8.00
Aphena Pharma Solutions — New York, LLC	Nasal decongestant/ inhaler/vapor			Levometamfetamine (l-desoxyephedrine)	50.00
Goldline Laboratories	Guiaphed Elixir	00182-1377	EL	Phenobarbital	4.00
Goldline Laboratories	Tedrigen Tablets	00182-0134	TB	Phenobarbital	8.00
Hawthorne Products, Inc.	Choate's Leg Freeze		LQ	Chloral hydrate	246.67
Parke-Davis & Co.	Tedral	00071-0230	TB	Phenobarbital	8.00
Parke-Davis & Co.	Tedral Elixir	00071-0242	EX	Phenobarbital	40.00
Parke-Davis & Co.	Tedral S.A.	00071-0231	TB	Phenobarbital	8.00
Parke-Davis & Co.	Tedral Suspension	00071-0237	SU	Phenobarbital	80.00
Parmed Pharmacy	Asma-Ese	00349-2018	TB	Phenobarbital	8.10
Rondex Labs	Azma-Aids	00367-3153	TB	Phenobarbital	8.00
Smith Kline Consumer	Benzedrex	49692-0928	IN	Propylhexedrine	250.00
Sterling Drug, Inc.	Bronkolixir	00057-1004	EL	Phenobarbital	0.80
Sterling Drug, Inc.	Bronkotabs	00057-1005	TB	Phenobarbital	8.00
Vicks Chemical Co.	Vicks Inhaler	23900-0010	IN	I-Desoxyephedrine	113.00
White Hall Labs	Primatene (P-tablets)	00573-2940	TB	Phenobarbital	8.00

AUTHORITY: section 195.015, RSMo Supp. 2022, and section 195.195, RSMo 2016. Material found in this rule previously filed as 19 CSR 30-1.010. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed Sept. 30, 2016, effective May 30, 2017. Emergency amendment filed Oct. 25, 2018, effective Nov. 4, 2018, expired May 2, 2019. Amended: Filed Oct. 25, 2018, effective April 30, 2019. Emergency amendment filed Oct. 30, 2020, effective Nov. 16, 2020, expired May 14, 2021. Amended: Filed Oct. 30, 2020, effective April 30, 2021. Emergency amendment filed Sept. 28, 2021, effective Oct. 13, 2021, expired April 10, 2022. Amended: Filed Sept. 28, 2021, effective March 30, 2022. Emergency amendment filed Sept. 12, 2022, effective Oct. 3, 2022, expired March 31, 2023. Amended: Filed Sept. 12, 2022, effective March 30, 2023.*

**Original authority: 195.015, RSMo 1971, amended 1989, 2014, 2020, and 195.195, RSMo 1957, amended 1971, 1989, 1993, 2014.*

19 CSR 30-1.004 List of Excepted Substances

PURPOSE: The Department of Health is authorized to except by rule any compound, mixture or preparation containing any stimulant or depressant substance if one or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system is included to negate the potential for abuse. The compounds, mixtures and preparations excluded are listed in this rule.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

(1) Excepted Stimulant or Depressant Compounds — Exempt Prescription Products. The listed drugs in dosage unit form and any other drug of the quantitative composition shown in Part 1300 to end of Title 21, the *Code of Federal Regulations*, April 1998 or which is the same except that it contains a lesser quantity of controlled substances or other substances which do not have a stimulant, depressant or hallucinogenic effect and which are restricted by law to dispensing or prescription, are excepted from the provisions of sections 195.030, 195.040, 195.050 and 195.100, RSMo as provided for in section 195.017.6(5) and .8(3), RSMo. The rules of the Drug Enforcement Administration, 21 CFR Part 1300 to the end of Title 21, are hereby incorporated by reference and made a part of this rule.

(2) Excepted Chemical Preparations — Exempt Chemical Preparations. The listed preparations in unit form and any other preparation of the quantitative composition shown in Part 1300 to end of Title 21, the *Code of Federal Regulations*, April 1998 which is the same except that it contains a lesser quantity of controlled substances or other substances which do not have a stimulant, depressant or hallucinogenic effect are excepted from the provisions of sections 195.030, 195.040, 195.050 and 195.110, RSMo as provided for in section 195.017.6(5) and .8(3), RSMo. The rules of the Drug Enforcement Administration, 21 CFR Part 1300 to the end of Title 21, are hereby incorporated by reference and made a part of this rule.

AUTHORITY: section 195.195, RSMo 1994. Material found in this rule previously filed as 19 CSR 30-1.020. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.006 List of Exempt Anabolic Steroid Products

PURPOSE: This rule maintains a list of anabolic steroid products excluded from 19 CSR 30-1.002(1)(C)5. in conformance with federal law.

(1) Persons who in the course of legitimate business handle products listed in the Table of Exempt Anabolic Steroid Products in this section shall be exempt from the registration, records, reports, prescriptions, physical security and import and export requirements associated with Schedule III substances.

(A) Trade Name	Company	NDC or DIN No.
1. Androgyn L.A.	Forest Pharmaceuticals, St. Louis, MO	0456-1005
2. Andro-Estro 90-4	Rugby Laboratories, Rockville Center, NY	0536-1605
3. depANDROGYN	Forest Pharmaceuticals, St. Louis, MO	0456-1020
4. DEPO-T.E.	Quality Research Pharmaceuticals, Camel, IN	52765-257
5. depTESTROGEN	Martica Pharmaceuticals, Phoenix, AZ	51698-257
6. Duomone	Wintec Pharmaceutical, Pacific, MO	52047-360
7. DURATESTRIN W.E.	Hauck, Alpharetta, GA	43797-016
8. DUO-SPAN II	Primedics Laboratories, Gardena, CA	0684-0102
9. Estratest	Solvay Pharmaceuticals, Marietta, GA	0032-1026
10. Estratest HS	Solvay Pharmaceuticals, Marietta, GA	0032-1023
11. Menogen	Sage Pharmaceuticals, Shreveport, LA	59243-570
12. Menogen HS	Sage Pharmaceuticals, Shreveport, LA	59243-560
13. PAN ESTRA TEST	Pan American Labs, Covington, LA	0525-0175
14. Premarin with Methyltestosterone	Ayerst Labs., Inc. New York, NY	0046-0879
15. Premarin with Methyltestosterone	Ayerst Labs., Inc., New York, NY	0046-0878
16. Synovex H Pellets in process	Syntex Animal Health, Palo Alto, CA	
17. Synovex H Pellets in process granulation	Syntex Animal Health, Palo Alto, CA	
18. Synovex Plus in-process granulation	Fort Dodge Animal Health, Fort Dodge, IA	
19. Synovex Plus in-process bulk pellets	Fort Dodge Animal Health, Fort Dodge, IA	
20. Testagen	Clint Pharmaceuticals, Nashville, TN	55553-257
21. TEST-ESTRO Cypionates	Rugby Laboratories, Rockville Centre, NY	0536-9470
22. Testoderm 4 mg/d	Alza Corp., Palo Alto, CA	17314-4608
23. Testoderm 6 mg/d	Alza Corp., Palo Alto, CA	17314-4609
24. Testoderm with Adhesive 6 mg/d	Alza Corp., Palo Alto, CA	17314-2836
25. Testoderm in-process film	Alza Corp., Palo Alto, CA	
26. Testoderm with Adhesive in-process film	Alza Corp., Palo Alto, CA	
Trade Name	**Company**	**NDC or DIN No.**
27. Testosterone Cyp 50 Estradiol Cyp 2	I.D.E.-Interstate, Amityville, NY	0814-7737
28. Testosterone Cypionate-Estradiol Cypionate Injection	Best Generics, No. Miami Beach, FL	54274-530
29. Testosterone Cypionate-Estradiol Cypionate Injection	Schein Pharmaceuticals, Port Washington, NY	0364-6611
30. Testosterone Cypionate-Estradiol Cypionate Injection	Steris Labs., Inc., Phoenix, AZ	0402-0257
31. Testosterone Cypionate-Estradiol Cypionate Injection	Goldline Labs, Ft. Lauderdale, FL	0182-3069
32. Testosterone Cypionate-Estradiol Cypionate Injection	The Upjohn Co., Kalamazoo, MI	0009-0253
33. Testosterone Enanthate-Estradiol Valerate Injection	Goldline Labs., Ft. Lauderdale, FL	0182-3073
34. Testosterone Enanthate-Estradiol Valerate Injection	Schein Pharmaceuticals, Port Washington, NY	0364-6618
35. Testosterone Enanthate-Estradiol Valerate Injection	Steris Labs., Inc., Phoenix, AZ	0402-0360
36. Tilapia Sex Reversal Feed (Investigational)	Rangen, Inc., Buhl, ID	
37. Tilapia Sex Reversal Feed (Investigational)	Ziegler Brothers, Inc. Gardners, PA	

AUTHORITY: section 195.195, RSMo 1994. Material found in this rule previouly filed as 19 CSR 30-1.025. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.008 List of Excluded Veterinary Anabolic Steroid Implant Products

PURPOSE: This rule maintains a list of veterinary anabolic steroid products excluded from 19 CSR 30-1.002(1)(C)5. in conformance with federal law.

(1) The following products containing an anabolic steroid that are expressly intended for administration through implants to cattle or other nonhuman species and which have been approved by the Secretary of Health and Human Services for such administration and are excluded from all schedules pursuant to section 195.017.5, RSMo.

Trade Name	Company	NDC or DIN No.
(A) Component E-H	Vetlife, Inc., Norcross, GA	021641-002
(B) Component E-H	Elanco, Scarborough, ON	01968327
(C) Component TE-S	Vetlife, Inc., Norcross, GA	021641-004
(D) Component T-H	Vetlife, Inc., Norcross, GA	021641-006
(E) Component T-S	Vetlife, Inc., Norcross, GA	021641-005
(F) F-TO	Animal Health, Upjohn International, Kalamazoo, MI	00093351
(G) Finaplix-H	Hoechst Roussel Vet, Somerville, NJ	12799-807-10
(H) Finaplix-S	Hoechst Roussel Vet, Somerville, NJ	12799-807-07
(I) Heifer-oid	Anchor Division, Boehringer Ingelheim, St. Joseph, MO	
(J) Heifer-oid	Bio-Ceutic Division, Boehringer Ingelheim, St. Joseph, MO	
(K) Heifer-oid	Ivy Laboratories, Inc., Overland Park, KS	
(L) Implus-H	The Upjohn Co., Kalamazoo, MI	0009-0434-01
(M) Implus-H	Upjohn Co., Animal Health Division, Orangeville, ON	06-0434-01 01968327
(N) Revalor-G	Hoechst Roussel Vet, Somerville, NJ	12799-811
(O) Revalor-H	Hoechst Roussel Vet, Somerville, NJ	12799-810
(P) Revalor-S	Hoechst Roussel Vet, Somerville, NJ	12799-809
(Q) Synovex H	Fort Dodge Labs, Fort Dodge, IA	0856-3901
(R) Synovex H	Syntex Laboratories, Palo Alto, CA	
(S) Synovex Plus	Fort Dodge Labs, Fort Dodge, IA	0856-3904

AUTHORITY: section 195.195, RSMo 1994 and 195.017, RSMo Supp. 1999. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.017, RSMo 1971, amended 1987, 1989, 1994, 1996, 1997, 1998 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.010 Schedules of Controlled Substances
(Rescinded November 30, 2000)

AUTHORITY: section 195.195, RSMo Supp. 1993. This rule was previously filed as 13 CSR 50-130.010 and 19 CSR 10-130.010. Original rule filed Jan. 31, 1972, effective April 1, 1972. Amended: Filed Oct. 4, 1972, effective Oct. 14, 1972. Amended: Filed April 4, 1973, effective April 14, 1973. Amended: Filed Sept. 28, 1973, effective Nov. 4, 1973. Amended: Filed Jan. 3, 1974, effective Jan. 13, 1974. Amended: Filed Oct. 9, 1974, effective Oct. 19, 1974. Amended: Filed July 17, 1975, effective July 27, 1975. Amended: Filed Oct. 8, 1975, effective Oct. 18, 1975. Refiled: March 24, 1976. Amended: Filed Oct. 12, 1976, effective Jan. 13, 1977. Amended: Filed March 15, 1977, effective March 24, 1977. Amended: Filed Nov. 14, 1977, effective Nov. 6, 1977. Amended: Filed Sept. 28, 1977, effective Jan. 13, 1978. Amended: Filed March 9, 1978, effective Feb. 24, 1978. Amended: Filed Oct. 2, 1978, effective Sept. 27, 1978. Amended: Filed Nov. 14, 1978, effective June 16, 1978. Amended: Filed Nov. 14, 1978, effective Oct. 25, 1978. Amended: Filed Feb. 13, 1979, effective Feb. 9, 1979. Amended: Filed Feb. 19, 1980, effective Feb. 11, 1980. Amended: Filed Oct. 14, 1980, effective July 24, 1980. Amended: Filed Oct. 14, 1980, effective Aug. 21, 1980. Amended: Filed Oct. 14, 1981, effective Oct. 30, 1980. Amended: Filed Oct. 14, 1981, effective May 8, 1981. Amended: Filed Oct. 14, 1981, effective Aug. 20, 1981. Amended: Filed Nov. 1, 1982, effective Dec. 11, 1982. Amended: Filed Jan. 12, 1983, effective Feb. 11, 1983. Amended: Filed March 11, 1983, effective April 1, 1983. Amended: Filed Sept. 2, 1983, effective Dec. 11, 1983. Amended: Filed Nov. 7, 1983, effective Dec. 11, 1983. Amended: Filed July 12, 1984, effective Aug. 11, 1984. Amended: Filed Sept. 20, 1984, effective Nov. 11, 1984. Amended: Filed Jan. 15, 1985, effective Feb. 11, 1985. Amended: Filed May 29, 1985, effective June 27, 1985. Amended: Filed July 24, 1985, effective Aug. 26, 1985. Amended: Filed Sept. 12, 1985, effective Oct. 11, 1985. Changed to 19 CSR 10-130.010, effective Oct. 11, 1985. Amended: Filed Jan. 3, 1986, effective Jan. 16, 1986. Changed to 19 CSR 30-1.010, effective Aug. 11, 1986. Amended: Filed April 17, 1987, effective May 14, 1987. Amended: Filed July 3, 1987, effective Aug. 27, 1987. Amended: Filed May 3, 1988, effective May 26, 1988. Amended: Filed Sept. 25, 1989, effective Oct. 27, 1989. Emergency amendment filed April 3, 1991, effective April 13, 1991, expired Aug. 10, 1991. Emergency amendment filed May 1, 1991, effective May 11, 1991, expired Sept. 7, 1991. Emergency amendment filed July 23, 1991, effective Aug. 2, 1991, expired Nov. 28, 1991. Amended: Filed April 3, 1991, effective Sept. 30, 1991. Amended: Filed May 1, 1991, effective Sept. 30, 1991. Amended: Filed March 2, 1992, effective Aug. 6, 1992. Amended: Filed July 6, 1993, effective Dec. 9, 1993. Emergency amendment filed Jan. 5, 1994, effective Jan. 15, 1994, expired May 14, 1994. Amended: Filed Jan. 5, 1994, effective July 30, 1994. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

***State v. Miller**, 588 SW2d 237 (Mo. App. 1979). Evidence of the presence of amphetamine is sufficient to support a controlled substances conviction; no quantitative analysis is necessary. Those rules refiled between January 1 and March 31, 1976 were not required to be published under section 536.021, RSMo. Also, courts must take judicial notice of the contents of the **Code of State Regulations**.*

***Selvey v. State**, 578 SW2d 64 (Mo. App. 1979). Phenmetrazine, originally established statutorily as a Schedule III controlled substance, was rescheduled by the Division of Health to Schedule II. Such a rescheduling is within the statutory power granted the Division of Health and does not usurp the legislative power of the general assembly.*

***State v. Davis**, 450 SW2d 168 (Mo. App. 1970). Statutes which direct the Division of Health to prepare a list of drugs classified as barbiturates and stimulants, the sale of which are made unlawful by statute, does not violate the **Missouri Constitution** prohibition in Article I, section 31 against delegation of authority to an agency to make a rule fixing a fine or imprisonment as punishment for its violation.*

19 CSR 30-1.011 Definitions

PURPOSE: This rule contains definitions which establish the

intended meaning of certain terms used throughout this chapter.

(1) As used in this chapter, the following terms shall have the meanings specified:

(A) Commercial container means any bottle, jar, tube, ampule or other receptacle in which a substance is held for distribution or dispensing to an ultimate user and, in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term commercial container does not include any package liner, package insert of other material kept with or within a commercial container, nor any carton, crate, drug or other package in which commercial containers are stored or are used for shipment of controlled substances;

(B) Controlled substances administration record means the form used to record information when administering individual drug doses to patients;

(C) Dispenser means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance;

(D) Hospice means a public agency or private organization or subdivision of either of these that is primarily engaged in providing care to dying persons and their families and meets the standards specified in 19 CSR 30-35;

(E) Hospital employee means a nurse, physician, pharmacist or other responsible patient-care employee;

(F) Individual practitioner means a physician, dentist, veterinarian, optometrist or other individual licensed, registered or otherwise permitted by the United States or Missouri to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy or an institutional practitioner;

(G) Institutional practitioner means a hospital or other person (other than an individual) licensed, registered or otherwise permitted by the United States or Missouri to dispense a controlled substance in the course of professional practice, but does not include a pharmacy;

(H) Long-term care facility means a nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients;

(I) Name means the official name, common or usual name, chemical name or brand name of a substance;

(J) Nurse means a registered or licensed practical nurse licensed under Chapter 335, RSMo;

(K) Patient care areas means any area of a hospital where medical attention is rendered to a patient;

(L) Pre-hospital emergency medical service means an emergency medical services system as defined in Chapter 190, RSMo providing services to persons prior to admission to a hospital;

(M) Prescription means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (For example, an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription.);

(N) Readily retrievable means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in a manner that they can be separated out from all other records; and/or records are kept on which certain items are asterisked, redlined, highlighted or in some other manner visually identifiable apart from other items appearing on the records; and records are provided within three working days of a request;

(O) Registration means a Missouri controlled substances registration;

(P) Reregistration means a registration issued to a person who was previously registered and whose application for reregistration was received by the Department of Health prior to the expiration of the previous registration;

(Q) Temporary location registration means a registration issued to an individual practitioner who:

1. Has a current Missouri professional license to practice and is registered with the Department of Health at the address listed on his/her professional license;

2. Has a federal Drug Enforcement Administration registration that is valid in Missouri;

3. Anticipates practicing in Missouri within the next 12 months;

4. Does not practice for more than 90 consecutive calendar days at any location;

5. Maintains a record of the date(s) and location(s) of all practice activity in Missouri and makes the record available to the Bureau of Narcotics and Dangerous Drugs. This record shall be retained for two years;

6. Maintains all required controlled substance records at each location;

7. Does not receive or stock controlled substances at any location;

(2) Any term not defined in this rule shall have the definition set forth in Chapter 195, RSMo.

AUTHORITY: section 195.195, RSMo 2000. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.013 Miscellaneous Fees

PURPOSE: This rule establishes and fixes certain fees and charges statutorily authorized to be made by the Department of Health in provisions codified in Chapters 195 and 610, RSMo.

(1) Fees for copies of public records or other documents:

(A) Copy, per page	$ 0.25
(B) Research fee, per hour	$15.00

(2) Payment of fee may be required in advance.

(3) Fees are nonrefundable.

AUTHORITY: section 195.030, RSMo Supp. 1999 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1997, 1999 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.015 Registrations and Fees

PURPOSE: This rule establishes fees for various types of registration, a late registration fee, manner of payment, and exemption from the registration fee.

(1) For each registration or re-registration to –

(A) Manufacture controlled substances, the registrant shall pay a fee of sixty-six dollars ($66);

(B) Distribute controlled substances, the registrant shall pay a fee of sixty-six dollars ($66);

(C) Dispense controlled substances listed in Schedules II–V including dispensing of controlled substances by individual practitioners in training programs or to conduct research or instructional activities with those substances, the registrant shall pay a fee of thirty dollars ($30);

(D) Conduct research or instructional activities with a controlled substance listed in Schedule I, the registrant shall pay a fee of thirty dollars ($30);

(E) Conduct chemical analysis with controlled substances listed in any schedule, the registrant shall pay a fee of thirty dollars ($30); and

(F) Import or export controlled substances listed in any schedule, the registrant shall pay a fee of sixty-six dollars ($66).

(2) Lapsed Registration Fee. A late charge of ten dollars ($10) must be submitted with the original registration fee if an application is submitted more than fifteen (15) days after a previous registration has expired.

(3) Time and Method of Payment and Refunds. Registration and re-registration fees shall be paid at the time the application for registration or re-registration is submitted for filing. This is a nonrefundable processing fee. Payment should be made in the form of an online credit card payment, payable to the Department of Health and Senior Services. Personal, certified, or cashier's checks, money orders, or other payments made in the form of stamps, foreign currency, or third-party endorsed checks will not be accepted. Applications and fees shall be submitted electronically online and applicants shall use the online payment system provided on the department's website. In the event the online application registration process becomes unavailable, applicants may contact the department for alternative options to apply for registration.

(4) Persons Exempt From Fee. The Department of Health and Senior Services shall exempt the following persons from payment of a fee for registration or re-registration:

(A) Any official or agency of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, Veterans Administration, or Public Health Service who is authorized to procure or purchase controlled substances for official use;

(B) Any official, employee or other civil officer, or agency of the United States or state or any political subdivision or agency who is authorized to purchase controlled substances, to obtain these substances from official stocks, to dispense or administer these substances, to conduct research, instructional activities, or chemical analysis with these substances, or any combination of them, in the course of his/her official duties or employment;

(C) In order to claim exemption from payment of a registration or re-registration fee, the registrant shall apply for exemption by completing appropriate sections of the application;

(D) Exemption from payment of a registration or re-registration fee does not relieve the registrant of any other requirements or duties prescribed by law; and

(E) Any registration that is exempt from payment pursuant to this section shall be valid only when authorized persons are conducting activities in the course of their official duties or employment at their government practice location. If the person conducts controlled substance activities away from his or her government practice location, the person shall apply and submit the required fee for a non-exempt registration.

AUTHORITY: sections 195.030 and 195.195, RSMo 2016. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011. Amended: Filed Aug. 10, 2022, effective Feb. 28, 2023.*

**Original authority: 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1997, 1999, 2014, and 195.195, RSMo 1957, amended 1971, 1989, 1993, 2014.*

19 CSR 30-1.017 Registration Process

PURPOSE: This rule establishes the period and expiration of registration, the process of applying for registration, and information required to complete an application for registration.

(1) Database and Survey Process.

(A) Applicants may apply for and receive a registration that is effective for up to twelve (12) months.

(B) Applicants shall apply through the department's electronic online system.

(C) Simultaneously with completing an application for a controlled substances registration, practitioners may also complete an annual voluntary census to assist the department in determining practitioner shortages and underserved regions of the state. Required questions and fields for controlled substance registrations are marked with an asterisk (*) in the electronic online system.

(2) Period of Registration.

(A) Any registration shall be current and effective for twelve (12) months from the date issued or until the expiration date assigned at the time the registration is issued. No person who is required to be registered shall conduct any activity for which registration is required without a current registration. No controlled substance activities shall take place after a registration expires until a new registration has been issued.

(B) At the time any registration is issued, the registration shall be assigned to one (1) of twelve (12) groups which shall correspond to the months of the year. The expiration date of all registrations within any group shall be the last day of the month designated for that group.

(C) Registrations for manufacturers and distributors may be assigned to a single group, and the expiration date may be less than twelve (12) months from the date the registration was issued.

(D) Training program registrations may be assigned to a single group, and the expiration date may be less than twelve (12) months from the date the registration was issued.

(E) A certificate of registration shall be made available online and printable to the registrant which shall include the name and address of the registrant, the expiration date of the registration, and a registration number for the convenience of identifying a registration or a registrant. The same registration number may be used for a new registration for the same person.

(3) Requirements for All Applicants.

(A) Any person who is required to be registered and who is not so registered may apply online for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is processed and the registration is issued. All applications are for new registrations.

(B) Applications for registration shall be made on online

forms designated by the Department of Health and Senior Services. Application for registration shall be completed online and submitted electronically via the Missouri Department of Health and Senior Services' website at https://health.mo.gov/safety/bndd/ along with the required fee.

(C) An application shall contain the electronic signature of the applicant and shall be provided to the Department of Health and Senior Services with any required fee. This is a non-refundable processing fee.

(D) An application which does not contain or is not accompanied by the required information or fee may be denied sixty (60) days after notifying the applicant of the deficiency.

(E) An application may be withdrawn by making a written request to the Department of Health and Senior Services.

(F) A person who is registered may conduct activities with controlled substances in Schedules II, III, IV, and V, as authorized by statute, unless a registration is restricted as to schedules or activities because of a settlement agreement, probation, or other disciplinary action taken by the Department of Health and Senior Services, the Drug Enforcement Administration, or a professional licensing board. Authority to conduct activities with controlled substances in Schedule I requires a separate application and registration.

(4) All applicants shall make full, true, and complete answers on the application. The Department of Health and Senior Services may require an applicant to submit documents or written statements of fact relevant to the application as considered necessary to determine whether the application should be granted. The failure of the applicant to provide these documents or statements within sixty (60) days after being requested to do so shall be considered to be a waiver by the applicant of an opportunity to present these documents or facts for consideration in granting or denying the application.

(5) Applications for Individual Practitioner Registrations. Applications by physicians, veterinarians, optometrists, podiatrists, and researchers for Missouri Controlled Substance Registrations shall include:

(A) The applicant's full legal name (first name, middle name, and last name), including any suffixes such as junior, senior, or III, gender, race, and ethnicity;

(B) A listing of all addresses and practice locations where controlled substance activities will be taking place. The applicant's street addresses, cities, zip codes, counties, and state. The number of hours worked per week for each location shall be provided for performing direct patient care (non-hospital), administration, research, teaching, in-patient hospital care, and other. The applicant shall also identify his or her primary, principle practice location, where he or she spends the most time. This will be the principle practice address that appears on the controlled substances registration. A physical street address is required and post office box addresses shall not be accepted;

(C) Whether the application is for a physician, veterinarian, optometrist, podiatrist, or researcher;

(D) His or her anticipated drug activities such as administering, prescribing, or dispensing;

(E) The required fee and fee information. If claiming an exemption from a fee, the applicant shall identify the name of the government agency that employs him or her;

(F) His or her business telephone number, fax number, email address, federal controlled substances registration number, if applicable; professional degree, if applicable; and professional license number, if applicable. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate the application is pending;

(G) Whether the applicant, or any officer of a corporate applicant, or individual employed by any applicant having access to controlled substances, has ever entered a plea of guilty, no contest, *nolo contendere*, or otherwise been convicted of any violation of any state or federal law related to the possession, manufacture, distribution, dispensing, or prescribing of controlled substances. If the answer is yes, the applicant shall provide an explanation;

(H) If the applicant is an individual or a registrant that holds a professional license, whether he or she is currently licensed and registered to practice his or her profession under the laws of this state;

(I) If the applicant is not an individual or registrant that holds a professional license, the applicant shall answer yes or no to whether the applicant is currently authorized to conduct business under the laws of this state;

(J) Previous Discipline. If the applicant currently holds or has previously held a state or federal controlled substance registration or state professional license or registration, the applicant shall answer yes or no to whether the applicant's license, registration, or application or renewal thereof has ever been surrendered, revoked, suspended, denied, restricted, or placed on probation and if any such action is pending. If the answer is yes, the applicant shall provide an explanation;

(K) Whether the applicant is abusing or has abused or been treated for or diagnosed with addiction regarding controlled substances during the past year. For purposes of this subsection, "abusing" or "abused" means using or having used a controlled substance in a manner not authorized under Chapter 195, RSMo;

(L) Copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (G) and (J) of this section, if the department does not already have them on file;

(M) The electronic signature of the individual applicant;

(N) His or her Social Security number and date of birth (MM/DD/YYYY);

(O) The date the application is signed;

(P) What drug schedules the applicant is requesting authority in; and

(Q) A listing of mid-level practitioners by name and license number with whom applicant has agreements pursuant to Chapter 334, RSMo.

(6) Applications for Pharmacies and Businesses. Applications for retail pharmacies and ambulance services, ambulatory surgery centers, analytical laboratories, correctional centers, distributors, exporters, hospices, hospitals, importers, manufacturers, narcotic treatment programs, long-term care facility E-kits, teaching institutions, researchers, or other applicants not listed in sections (5)–(8), shall include:

(A) The applicant's full legal name, and if applicable, d/b/a name;

(B) The applicant's tax ID number, if applicable;

(C) The applicant's facility license number, if applicable, and federal controlled substances registration number. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate an application is pending;

(D) The applicant's email address;

(E) The applicant's principle Missouri business street address, city, state, county, and zip code as it will appear on the controlled substances registration certificate. Post office box

numbers shall not be accepted. A separate mailing address may also be provided;

(F) The applicant's business telephone number and fax number;

(G) The applicant's type of business activity, licensure type, licensure agency, and license number;

(H) What controlled substance schedules the applicant is requesting authority in;

(I) The applicant's criminal history information as it pertains to controlled substance laws. The applicant shall answer yes or no as to whether the owner, CEO or administrator, corporate officer, medical director, pharmacist in charge, or any employee with access to controlled drugs has ever pled guilty, no contest, *nolo contendere*, or ever been convicted of any violation of state or federal law relating to controlled substances;

(J) Whether there are any previous or pending disciplinary actions regarding the applicant's professional license or any controlled substance registration, whether the applicant's privileges or authority have been revoked, surrendered, suspended, restricted, or placed on probation, or if any application for a state license or any drug registration has ever been denied;

(K) The application shall be submitted online with the required fee and fee information. If claiming an exemption from a fee, the applicant must identify the name of the government agency;

(L) Copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (I) and (J) of this section, if the department does not already have them on file;

(M) If the applicant is a retail business, the applicant shall provide a letter from the Missouri Department of Revenue that documents that no Missouri taxes are due and the applicant is in good standing; and

(N) The applicant shall electronically sign and date an application. An application may be signed by the owner, chief executive officer or administrator, corporate officer, medical director, or pharmacist in charge.

(7) Applications for Dentists. Applications for dentists with the degrees of D.D.S. or D.M.D. shall include:

(A) The applicant's full legal name (first name, middle name, and last name), including any suffixes such as junior, senior, or III;

(B) His or her Social Security number and date of birth (MM/DD/YYYY);

(C) The applicant's federal controlled substances registration number. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate the application is pending;

(D) The applicant's gender, race, and ethnicity;

(E) The applicant's email address;

(F) The applicant's primary specialty and any board certification;

(G) Whether the applicant is licensed to practice and conduct activities and the applicant's licensure type, license number, and name of licensing agency;

(H) What drug schedules the applicant is requesting to conduct activities in;

(I) The applicant's anticipated drug activities such as administering, prescribing, or dispensing;

(J) The applicant's street addresses, city, zip code, county, and state of their primary, principle practice location, where they spend the most time. This will be the address that appears on the controlled substances registration. Post office box numbers shall not be accepted. Applicants shall also provide any secondary practice locations and the number of chair-side work hours per week at each location. The number of hours worked per week for each location shall be provided for performing direct patient care (non-hospital), administration, research, teaching, in-patient hospital care, and other;

(K) The applicant's business phone number and fax number;

(L) The applicant's criminal history information as it pertains to controlled substance laws. The applicant shall answer yes or no as to whether the applicant or any employees with access to controlled drugs have ever pled guilty, no contest, *nolo contendere*, or ever been convicted of any violation of state or federal law relating to controlled substances;

(M) Information regarding any previous or pending disciplinary actions regarding the applicant's professional license or any controlled substance registration, as to whether the applicant's privileges or authority have been revoked, surrendered, suspended, restricted, or placed on probation, or if any application for a state license or any drug registration has ever been denied;

(N) Whether the applicant is abusing or has abused or been treated for or diagnosed with addiction regarding controlled substances during the past year. For purposes of this subsection, "abusing" or "abused" means using or having used a controlled substance in a manner not authorized under Chapter 195, RSMo;

(O) The application shall be submitted with the required fee and fee information. If claiming an exemption from a fee, the applicant shall identify the name of the government agency that employs him or her;

(P) The applicant shall provide copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (L) and (M) of this section, if the department does not already have them on file; and

(Q) The applicant shall sign and date an application submitted electronically.

(8) Applications for Mid-Level Practitioners. Applications for mid-level practitioners as defined by 21 CFR 1300.01(b)(28) such as advanced practice nurses and physician assistants shall include:

(A) The applicant's full legal name (first name, middle name, and last name), including any suffixes such as junior, senior, or III;

(B) The applicant's social security number and date of birth (MM/DD/YYYY);

(C) The applicant's federal controlled substances registration number. If the applicant has an application pending for a federal controlled substances registration number, the applicant shall indicate the application is pending;

(D) The applicant's gender, race, and ethnicity;

(E) The applicant's email address;

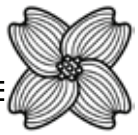
(F) Whether the applicant is licensed to practice and conduct activities and the applicant's licensure type, license number, and name of licensing agency;

(G) What controlled substance schedules (III, IV, or V) the applicant is requesting to conduct activities in;

(H) Which physicians the applicant has collaborative or supervision agreements with;

(I) A copy of the applicant's collaborative or supervision agreements with physicians, and a list of controlled substances from each physician that the mid-level practitioner is authorized to conduct activities with, in that agreement;

(J) The applicant's street address, city, zip code, county, and state of the applicant's primary, principle practice location. This will be the principle address that appears on the controlled



substances registration. Post office boxes shall not be accepted. Applicants shall also provide any secondary practice location addresses and the number of hours worked per week for each location for performing direct patient care (non-hospital), administration, research, teaching, in-patient hospital care, and other;

(K) The applicant's business phone number and fax number;

(L) The applicant's criminal history information as it pertains to controlled substance laws. The applicant shall answer yes or no as to whether the applicant or any employee with access to controlled drugs has ever pled guilty, no contest, *nolo contendere*, or ever been convicted of any violation of state or federal law relating to controlled substances;

(M) Information regarding any previous or pending disciplinary actions regarding the applicant's professional license or any controlled substance registration, as to whether the applicant's privileges or authority have been revoked, surrendered, suspended, restricted, or placed on probation, or if any application for a state license or any drug registration has ever been denied;

(N) Whether the applicant has abused or been treated for or diagnosed with addiction regarding controlled substances during the past year. For purposes of this subsection, "abusing" or "abused" means using or having used a controlled substance in a manner not authorized under Chapter 195, RSMo;

(O) The application shall be submitted with the required fee and fee information. If claiming an exemption from a fee, the applicant shall identify the name of the government agency that employs the applicant;

(P) The applicant shall provide copies and attachments of any guilty pleas, convictions, or disciplinary actions identified in subsections (L) and (M) of this section, if the department does not already have them on file; and

(Q) The applicant shall sign and date an application submitted electronically.

AUTHORITY: section 195.195, RSMo 2016. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011. Amended: Filed Aug. 10, 2022, effective Feb. 28, 2023.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993, 2014.*

19 CSR 30-1.019 Registration Location

PURPOSE: This rule establishes requirements for the physical location of a registration.

(1) A controlled substance registration shall be issued at a U.S. Postal Service street address.

(2) A controlled substance registration shall be issued to an individual practitioner at a Missouri practice location where controlled substance and other patient care activities occur.

AUTHORITY: section 195.195, RSMo 2000. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.020 List of Excepted Substances
(Rescinded November 30, 2000)

AUTHORITY: section 195.195, RSMo Supp. 1989. This rule was previously filed as 13 CSR 50-130.020. Original rule filed Sept. 28, 1977, effective Jan. 13, 1978. Amended: Filed Nov. 14, 1978, effective Dec. 11, 1978. Amended: Filed Oct. 12, 1979, effective Nov. 11, 1979. Amended: Filed Oct. 14, 1981, effective Nov. 2, 1981. Amended: Filed Nov. 1, 1982, effective Dec. 11, 1982. Amended: Filed Nov. 7, 1983, effective Dec. 11, 1983. Amended: Filed Oct. 2, 1991, effective Feb. 6, 1992. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

19 CSR 30-1.023 Registration Changes

PURPOSE: This rule establishes procedures for modifying an existing registration, describes the conditions under which a registration automatically terminates, and prohibits the transfer of a registration.

(1) Modification of Registration.

(A) Any registrant may apply to modify his/her registration to authorize the handling of controlled substances in additional schedules by submitting a request in writing to the department. No fee shall be required to be paid for the modification. The application for modification shall be handled in the same manner as an application for registration.

(B) Any registrant may request to modify his or her name or address as shown on the registration provided that such a modification does not constitute a change of ownership or location. The request shall be made in writing and no fee shall be required to be paid for the modification. The request for changes may be submitted electronically using the department's online database system. Requests submitted in paper form shall contain the registrant's signature.

(C) When the registrant's name or address as shown on the registration changes, the registrant shall notify the Department of Health and Senior Services in writing, including the registrant's signature, prior to or within thirty (30) days subsequent to the effective date of the change. No fee shall be required to be paid for the modification.

(D) Collector of Unwanted Controlled Substances. A current registrant with the department may request to have their registration modified to authorize the collection of unwanted controlled substances. Requests shall be submitted in writing to the Bureau of Narcotics and Dangerous Drugs, PO Box 570, Jefferson City, MO, 65102-0570. Requests shall provide the requesting registrant's name, address, and current Missouri Controlled Substances Registration number. Requests shall identify the method of collection such as either a collection receptacle box or mail-back return system, or both, and shall identify the exact physical address of the receptacle. Collection receptacles located in long term care facilities shall be maintained by a retail pharmacy or a hospital/clinic with an on-site pharmacy. The bureau will respond to the registrant's request in writing. Registrants authorized by the department to collect unwanted controlled substances shall comply with all requirements for record keeping and security in accordance with federal regulations. The privilege of being a collector may be terminated if the registrant's authority to collect is terminated by the United States Drug Enforcement Administration, a judicial order, an act by a state licensing board or agency, or if the collector's registration is restricted as a matter of public discipline by the department. An authorized collector who wishes to cease being a collector shall notify the

bureau in writing of the date that collections will cease.

(2) Termination of Registration.

(A) The registration of any person shall terminate –

1. On the expiration date assigned to the registration at the time the registration was issued;

2. If and when the person dies;

3. If and when the person ceases legal existence;

4. If and when a business changes ownership, except –

A. The registration shall not terminate for thirty (30) days from the effective date of the change if the new owner applies for a registration within the thirty- (30-) day period and the corresponding Drug Enforcement Administration registration remains effective as provided for by the Drug Enforcement Administration;

5. If and when the person discontinues business or changes business location, except –

A. The registration shall not terminate for thirty (30) days from the effective date of the change if the person applies for a new registration or modification within the thirty- (30-) day period; or

6. Upon the written request of the registrant.

(B) A mid-level practitioner's registration shall be contingent upon the physician with whom he or she has entered into an agreement pursuant to Chapter 334, RSMo, having a current and valid registration. When such physician's registration expires, closes, or is no longer valid, any mid-level practitioner(s) with whom he or she has entered into an agreement shall no longer have controlled substance authority. The mid-level practitioner(s) shall cease controlled drug activities until the physician has obtained a new registration or the mid-level practitioner(s) obtain(s) another agreement with another physician pursuant to Chapter 334, RSMo. Mid-level practitioners and any physician with whom he or she has entered into an agreement pursuant to Chapter 334, RSMo, shall notify the Department of Health and Senior Services of the termination of any such agreement.

(C) Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Department of Health and Senior Services of the effective date of this action and promptly return his/her registration certificate to the Department of Health and Senior Services.

(3) Transfer of Registration. No registration or any authority conferred by registration shall be assigned or otherwise transferred.

AUTHORITY: section 195.195, RSMo Supp. 2018. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003. Amended: Filed April 29, 2011, effective Nov. 30, 2011. Emergency amendment filed Sept. 17, 2018, effective Sept. 27, 2018, expired March 25, 2019. Amended: Filed Sept. 17, 2018, effective March 30, 2019.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993, 2014.*

19 CSR 30-1.025 List of Exempt Anabolic Steroid Products
(Rescinded November 30, 2000)

AUTHORITY: section 195.015.4, RSMo Supp. 1989. Original rule filed July 6, 1993, effective Dec. 9, 1993. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

19 CSR 30-1.026 Separate Registrations

PURPOSE: This rule defines the requirements for controlled substance registrations for separate activities and for separate sites, and defines when a separate registration is not required.

(1) Independent Activities. The following eight groups of activities are deemed to be independent of each other and require separate registration:

(A) Manufacturing controlled substances;

(B) Distributing controlled substances, except:

1. A dispenser distributing less than 5% of the total combined dosage units of controlled substances distributed and dispensed in a calendar year shall be exempt from obtaining a separate registration for distributing;

2. A dispenser distributing more than 5% of the total combined dosage units of controlled substances distributed and dispensed in a calendar year must obtain a separate registration as a distributor but shall be exempt from maintaining separate inventories under 19 CSR 30-1.042;

(C) Dispensing controlled substances listed in Schedules II–V;

(D) Conducting research and instructional activities with controlled substances listed in Schedule I;

(E) Conducting research with controlled substances listed in Schedules II–V;

(F) Conducting a narcotic treatment program with narcotic controlled substances listed in Schedules II–V;

(G) Conducting instructional activities with controlled substances listed in Schedules II–V;

(H) Importing controlled substances;

(I) Exporting controlled substances;

(J) Conducting chemical analysis with controlled substances listed in any schedule.

(2) No activity shall be conducted with any controlled substance in any schedule not requested for and shown on the current registration.

(3) Separate Locations. A separate registration is required for each principal place of business or professional practice at one (1) general physical location where controlled substances are manufactured, distributed, or dispensed by a person.

(A) For purposes of registration only, the following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

1. A warehouse where controlled substances are stored by or on behalf of a registered person, unless these substances are distributed directly from the warehouse to registrants other than the registered person or to persons not required to register;

2. An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains these substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders;

3. An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at the office and where no supplies of controlled substances are maintained;

4. A location on the immediate or contiguous property of a hospital, provided that the location is owned and operated by the hospital and controlled substances are not dispensed for use away from the location;

5. A separate location from a registered pre-hospital emergency medical service location where an emergency vehicle is housed that does not have a permanent location of operation; and

6. A pre-hospital emergency medical service located outside the state of Missouri that renders assistance to a pre-hospital emergency medical service located in the state of Missouri under a mutual aid contract in the case of an emergency, major catastrophe, or other unforeseen event that jeopardizes the ability of the local Missouri pre-hospital emergency medical service to promptly respond.

(B) A separate registration is not required for each separate practice location for an individual practitioner who has a temporary location registration.

AUTHORITY: section 195.195, RSMo 2016. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Oct. 30, 2020, effective April 30, 2021.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993, 2014.*

19 CSR 30-1.027 Investigative and Administrative Procedures

PURPOSE: This rule establishes procedures for the handling and disposition of information indicating violations of Chapter 195, RSMo by the Department of Health, pursuant to the mandates of section 195.040.

(1) The Department of Health may allow officers of state and federal administrative agencies to attend and participate in informal conferences conducted with Missouri controlled substances registrants, Missouri regulated chemical registrants or applicants in order to assist the Department of Health in its deliberations.

AUTHORITY: section 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.030 Requirements for Controlled Substances Registration

(Rescinded November 30, 2000)

AUTHORITY: section 195.195, RSMo 1994. This rule was previously filed as 13 CSR 50-131.010. Original rule filed Jan. 31, 1972, effective April 1, 1972. Amended: Filed April 12, 1983, effective July 11, 1983. Amended: Filed May 31, 1989, effective Oct. 1, 1989. Amended: Filed Nov. 26, 1991, effective April 9, 1992. Amended: Filed Aug. 26, 1992, effective April 8, 1993. Amended: Filed Nov. 1, 1994, effective June 30, 1995. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

19 CSR 30-1.031 Physical Security Requirements

PURPOSE: This rule requires applicants and registrants to maintain security controls and procedures to prevent theft and diversion of controlled substances.

(1) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Department of Health shall use the security requirement set forth in 19 CSR 30-1.032–19 CSR 30-1.034 as standards for the physical security controls and operating procedures necessary to prevent diversion. Substantial compliance with these standards may be deemed sufficient by the Department of Health after evaluation of the overall security system and needs of the applicant or registrant.

(2) Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. If a controlled substance is transferred to a different schedule, or a noncontrolled substance is listed on any schedule, or the quantity of controlled substances in the possession of the registrant in normal business operations significantly increases, physical security controls shall be expanded and extended accordingly.

(3) All registrants who receive or transfer substantial quantities of controlled substances in normal business operations shall employ security procedures to guard against in-transit losses.

AUTHORITY: section 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.032 Security for Nonpractitioners

PURPOSE: This rule describes specific actions required of nonpractitioner registrants to maintain effective security.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the federal Drug Enforcement Administration (DEA) or with the Department of Health and Senior Services to determine that the person is registered to possess the controlled substance.

(2) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Department of Health and Senior Services of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

(3) The registrant shall notify the Department of Health and Senior Services of any theft or significant loss of any controlled substances upon discovery of this theft or loss.

(A) The registrant shall complete and submit a Report of Loss, Theft or Diversion of Controlled Substances or Regulated Chemicals to the Department of Health and Senior Services no later than seven (7) business days after the discovery of such a loss. If the extent of the loss cannot be fully determined in

that time frame, the registrant shall contact the Department of Health and Senior Services to request permission to submit an interim report and arrange for a complete report to be completed and submitted. The registrant may attach a copy of a completed Drug Enforcement Administration Loss Form in lieu of completing the back or second page of a Report of Loss, Theft or Diversion of Controlled Substances or Regulated Chemicals form. In the event of theft, diversion or suspected theft or diversion, the report submitted to the Department of Health and Senior Services shall be accompanied by or followed by a summary of the internal investigation performed, the outcome of the investigation, and a copy of any law enforcement agency report completed if applicable.

(B) If an insignificant amount of a controlled substance is lost during lawful activities authorized under Chapter 195, RSMo, the reason for the loss or a description of what occurred, the name of the drug and the amount lost shall be documented in writing, signed by the registrant and attached or filed with the last completed annual inventory.

(4) The registrant shall not distribute any controlled substance as a complimentary sample to any potential or current customer without the prior written request of the customer, to be used only for satisfying the legitimate medical needs of patients of the customer and only in reasonable quantities. The request must contain the name, address and registration number of the customer and the name of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements for order forms shall be complied with for any distribution of a controlled substance listed in Schedule I or II.

(5) Entities registered with the Department of Health and Senior Services as distributors shall be deemed to have met security requirements for storage of Schedule V controlled substance drug products containing ephedrine or pseudoephedrine if those products are stored in compliance and consistent with the regulated chemicals requirements set forth by the United States Drug Enforcement Administration and 21 CFR 1309.71 which is hereby incorporated by reference in this rule, as published on April 1, 2005 by the U.S. Government Printing Office, U.S. Superintendent of Documents, Washington, DC 20402-001; www.gpoaccess.gov/cfr/retrieve.html. This rule does not incorporate any subsequent amendments or additions. Distributors will be required to conduct background checks on employees with access to these substances and to report losses of controlled substances as required in 19 CSR 30-1.034.

AUTHORITY: sections 195.017, RSMo Supp. 2005 and 195.195, RSMo 2000. Original rule filed April 14, 2000, effective Nov. 30, 2000. Emergency amendment filed Aug. 18, 2005, effective Aug. 28, 2005, expired Feb. 23, 2006. Amended: Filed Sept. 1, 2005, effective Feb. 28, 2006.*

**Original authority: 195.017, RSMo 1971, amended 1987, 1989, 1994, 1996, 1997, 1998, 2001, 2005 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.033 Hearing Procedures on Controlled Substances Registration

(Rescinded November 30, 2000)

AUTHORITY: sections 195.040.11 and 195.195, RSMo Supp. 1989. Original rule filed Aug. 26, 1992, effective April 8, 1993. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

19 CSR 30-1.034 Security for Practitioners

PURPOSE: This rule describes specific actions required of practitioner registrants to maintain effective security. This rule also creates and defines the form which must be used by a registrant to report any theft or loss of controlled substances to the Department of Health.

(1) Physical Security.

(A) Controlled substances listed in Schedules I and II shall be stored in a securely locked, substantially constructed cabinet.

(B) Controlled substances listed in Schedules III, IV and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse these substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(C) This rule also shall apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.

(2) Other Security.

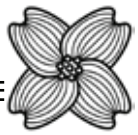
(A) The registrant shall not employ as an agent or employee who has access to controlled substances any person who has been found guilty or entered a plea of guilty or *nolo contendere* in a criminal prosecution under the laws of any state or of the United States for any offense related to controlled substances or who has had an application for a state or federal controlled substance registration denied or has had his/her registration revoked or surrendered for cause at any time. For purposes of this subsection, the term for cause means a surrender in place of or as a consequence of any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

1. A registrant may apply in writing to the Department of Health and Senior Services for a waiver of subsection (2)(A) of this rule for a specific employee.

2. The Department of Health and Senior Services may issue a written waiver to any registrant upon determination that a waiver would be consistent with the public health and safety. In making this determination, the Department of Health and Senior Services shall consider – the duties of the employee, the circumstances surrounding the conviction, the length of time since the conviction was entered, whether a waiver has been granted by the federal Drug Enforcement Administration (DEA) pursuant to 21 CFR 1301.76, the security measures taken by the employer to prevent the theft and diversion of controlled substances, and any other factors consistent with public health and safety.

(B) A registrant shall notify the Department of Health and Senior Services of the theft, diversion or significant loss of any controlled substances or regulated chemicals upon discovery.

1. The registrant shall complete and submit a report of the loss or diversion of controlled substances to the Department of Health and Senior Services no later than seven (7) business days after the discovery of such a loss. The loss report form shall contain the following information: name and address of registrant, business phone number; Missouri Controlled Substance Registration Number; federal Drug Enforcement Administration Registration number; date of theft or loss; date of discovery of theft or loss; county of location; principal type of registration such as M.D., D.O., D.P.M., O.D., D.V.M., D.D.S., D.M.D., A.N.P., emergency medical service, pharmacy, hospital, manufacturer, nursing home kit, narcotic treatment program, teaching institution, distributor, importer, exporter,



or other specified business; whether or not the loss or theft was reported to law enforcement; the name and phone number of the law enforcement agency reported to; the number of losses or thefts the registrant has experienced in the past twenty-four (24) months; the type of loss or diversion such as, break in/burglary, robbery, employee theft, forged or falsified records, lost in transit, or other explained type of loss; if lost in transit, the name of the common carrier and name of consignee; the name(s) of the individual diverting controlled substances who was responsible for the theft or loss; copy of registrant's internal investigative report involving the loss or theft; the full name, date of birth and Social Security number of the individual(s) responsible for the theft or diversion, if known; a copy of the police report if law enforcement was notified; if the loss or diversion was in transit, identify the origin of the delivery, the name of the carrier(s) used and the name of the consignee; a list of all controlled substances lost, stolen or diverted by their generic name, trade name, the dosage strength, dosage form and quantity; the signature of the person completing the loss report and their title and the date of their signature. If the extent of the loss cannot be fully determined in that time frame, the registrant shall contact the Department of Health and Senior Services to request permission to submit an interim report and arrange for a complete report to be completed and submitted. The registrant may attach a copy of a completed Drug Enforcement Administration Loss Form in lieu of completing the back or second page of a loss report form provided by the Department of Health and Senior Services. In the event of theft, diversion or suspected theft or diversion, the report submitted to the Department of Health and Senior Services shall be accompanied by or followed by a summary of the internal investigation performed, the outcome of the investigation, and a copy of any law enforcement agency report completed if applicable.

2. If an insignificant amount of a controlled substance is lost during lawful activities authorized under Chapter 195, RSMo, the reason for the loss or a description of what occurred, the name of the drug and the amount lost shall be documented in writing, signed by the registrant and attached or filed with the last completed annual inventory.

AUTHORITY: section 195.195, RSMo 2000. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 31, 2003, effective July 30, 2003.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.035 Requirements for Prescribing, Dispensing and Administering Controlled Substances
(Rescinded November 30, 2000)

AUTHORITY: sections 195.040.3(2), 195.050.6 and 195.195, RSMo 1994. Original rule filed Nov. 14, 1988, effective Feb. 24, 1989. Amended: Filed Aug. 26, 1992, effective April 8, 1993. Amended: Filed Nov. 1, 1994, effective June 30, 1995. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

19 CSR 30-1.036 Disposing of Unwanted Controlled Substances
(Rescinded November 30, 2000)

AUTHORITY: section 195.050.6, RSMo 1986. Original rule filed Jan. 18, 1989, effective April 27, 1989. Rescinded: Filed April 14, 2000, effective Nov. 30, 2000.

19 CSR 30-1.040 Dispensing and Distribution of Controlled Substances in Certain Situations
(Rescinded July 30, 2003)

AUTHORITY: section 195.195, RSMo 1986. This rule was previously filed as 13 CSR 50-132.010. Original rule filed Jan. 31, 1972, effective April 1, 1972. Rescinded: Filed Jan. 31, 2003, effective July 30, 2003.

19 CSR 30-1.041 Records Requirements

PURPOSE: This rule defines the record keeping and inventory requirements for various classes of registrants.

(1) Persons Required to Keep Records.

(A) Each registrant shall maintain the records and inventory required by 19 CSR 30-1.041–19 CSR 30-1.052, except as exempted by 19 CSR 30-1.041–19 CSR 30-1.052.

(B) Registered individual practitioners and institutional practitioners are required to keep records with respect to controlled substances which are prescribed, administered or dispensed.

(C) A registered person using any controlled substance in research conducted in conformity with an exemption granted under section 505(i) or 512(j) of the federal Food, Drug and Cosmetic Act (21 U.S.C. 355(i) or 360(j)) at a registered establishment which maintains records in accordance with either of those sections is not required to keep records if s/he notifies the Department of Health of the name, address and registration number of the establishment maintaining these records.

(D) A registered person using any controlled substance in preclinical research or in teaching at a registered establishment which maintains records with respect to these substances is not required to keep records if s/he notifies the Department of Health of the name, address and registration number of the establishment maintaining the records.

(E) Notice required by subsection (1)(D) of this rule shall be given at the time the person applies for registration or re-registration and shall be made in the form of an attachment to the application, which shall be filed with the application.

(2) Maintenance of Records and Inventories. Every inventory and other record required to be kept under 19 CSR 30-1.041–19 CSR 30-1.052, shall be kept by the registrant and be available, for at least two years from the date of the inventory or record, for inspecting and copying by authorized employees of the Department of Health, except that financial and shipping records (such as invoices and packing slips, but not executed order forms) may be kept at a central location rather than at the registered location if the registrant obtains from the Department of Health approval of his/her central record keeping system and a permit to keep central records. The permit to keep central records shall be subject to the following conditions:

(A) The permit shall specify the nature of the records to be kept centrally and the exact location where the records will be kept;

(B) The registrant agrees to deliver all or any part of these records to the registered location within three working days of receipt of a written request from the Department of Health for these records and if the Department of Health chooses to

do so in lieu of requiring delivery of records to the registered location, to allow authorized employees of the Department of Health to inspect the records at the central location upon request by the employees without a warrant of any kind;

(C) The failure of the registrant to perform his/her agreements under the permit shall revoke, without further action, the permit and all other such permits held by the registrant under other registrations. In the event of a revocation of other permits under subsection (2)(C) of this rule, the registrant, within 30 days after the revocation, shall comply with the requirement that all records be kept at the registered location.

(3) Each registered individual practitioner, institutional practitioner, manufacturer, distributor, importer and exporter shall maintain inventories and records of controlled substances as follows:

(A) Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant;

(B) Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the registrant or in a form that the information required is readily retrievable from the ordinary business records of the registrant.

(4) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(A) Inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy and prescriptions for these substances shall be maintained in a separate prescription file;

(B) Inventories and records of controlled substances listed in Schedules III, IV and V shall be maintained either separately from all other records of the pharmacy or in a form that the information required is readily retrievable from ordinary business records of the pharmacy and prescriptions for those substances shall be maintained in a separate prescription file.

AUTHORITY: sections 195.050 and 195.195, RSMo 1994 and 195.030, RSMo Supp. 1999. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.030, RSMo 1939, amended 1971, 1989, 1993, 1997, 1999; 195.050, RSMo 1939, amended 1971, 1989; and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.042 Inventory Requirements

PURPOSE: This rule defines requirements for the form and maintenance of controlled substance inventories.

(1) General Requirements.

(A) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory was taken. Controlled substances shall be deemed to be on hand if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

(B) A separate inventory shall be made by a registrant for each registered location. In the event controlled substances are in the possession or under the control of the registrant at a location for which s/he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.

(C) A separate inventory shall be made by a registrant for each independent activity for which s/he is registered.

(D) A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken.

(E) An inventory must be maintained in a permanent written, typewritten or printed form. An inventory taken by use of an oral recording device must be transcribed promptly.

(2) Initial Inventory Date.

(A) Every person required to keep records who is registered with the Department of Health after May 1, 1971 and who was not registered previously shall take an inventory of all stocks of controlled substances on hand on the date s/he first engages in the manufacture, distribution or dispensing of controlled substances.

(B) Compliance with federal initial inventory date requirements is deemed satisfactory. Duplicate inventories are not required.

(3) Annual Inventory Date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least once a year. The annual inventory may be taken on any date that is within one year of the previous annual inventory date.

(4) Inventory Date for Newly Controlled Substances. On the effective date of a rule by the Department of Health adding a substance to any schedule of controlled substances, which substance was not listed immediately prior to that date in any such schedule, every registrant required to keep records who is manufacturing, distributing or dispensing that substance shall take inventory of all stocks of the substance on hand. After that, this substance shall be included in each inventory made by the registrant.

(5) Inventories of Manufacturers. Each registered manufacturer shall include the following information in his/her inventory:

(A) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or noncontrolled substances in finished form, the name of the substance and the total quantity of the substance to the nearest metric unit weight consistent with unit size (except that for inventories made in 1971, *avoirdupois* weights may be utilized where metric weights are not readily available);

(B) For each controlled substance in the process of manufacture on the inventory date the name of the substance, the quantity of the substance in each batch, stage of manufacture, or both, identified by the batch number or other appropriate identifying number and the physical form which the substance is to take upon completion of the manufacturing process (for example, granulations, tablets, capsules or solutions), identified by the batch number or other appropriate identifying number and if possible the finished form of the substance (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number or volume;

(C) For each controlled substance in finished form, the name of the substance; each finished form of the substance (for example, ten milligram (10 mg) tablet or ten milligram (10

mg) concentration per fluid ounce or milliliter); the number of units or volume of each finished form in each commercial container (for example, four 100 tablet bottles or three milliliter (3 ml) vials); the number of commercial containers of each finished form (for example, four 100 tablet bottles or six three milliliter (3 ml) vials);

(D) For each controlled substance not included in subsections (5)(A)–(C) of this rule (for example, damaged, defective or impure substances awaiting disposal, substances held for quality control purposes or substances maintained for extemporaneous compoundings), the name of the substance; the total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; the reason for the substance being maintained by the registrant and whether the substance is capable of use in the manufacture of any controlled substance in finished form.

(6) Inventories of Distributors. Each registered distributor shall include in his/her inventory the same information required of manufacturers in subsections (5)(C) and (D) of this rule.

(7) Inventories of Dispensers and Researchers. Each person registered to dispense or conduct research with controlled substances and required to keep records shall include in his/her inventory the same information required of manufacturers in subsections (5)(C) and (D) of this rule. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

(A) If the substance is listed in Schedule I or II, s/he shall make an exact count or measure of the contents;

(B) If the substance is listed in Schedule III, IV or V, s/he shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case s/he must make an exact count of the contents.

(8) Inventories of Importers and Exporters. Each registered importer or exporter shall include in his/her inventory the same information required of manufacturers in subsections (5)(A), (C) and (D) of this rule. Each registered importer and exporter who also is registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that actually are separated from his/her stocks as a manufacturer or as a distributor (for example, in-transit or in storage for shipment).

(9) Inventories for Chemical Analysts. Each analytical laboratory registered to conduct chemical analysis with controlled substances shall include in its inventory the same information required of manufacturers in subsections (5)(A), (C) and (D) of this rule as to substances which have been manufactured, imported or received by the laboratory conducting the inventory. If less than one kilogram (1 kg) of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I) or less than twenty grams (20 g) of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide) or less than point five gram (0.5 g) of lysergic acid diethylamide, is on hand at the time of inventory, those substances need not be included in the inventory. Laboratories of the division may process up to one hundred fifty grams (150 g) of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances.

AUTHORITY: sections 195.030, RSMo Supp. 1999 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000. ***

**Original authority: 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1997, 1999 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

***Pursuant to Executive Order 21-07, 19 CSR 30-1.042, section (3) was suspended from March 31, 2020 through May 1, 2021.*

19 CSR 30-1.044 Continuing Records General Requirements

PURPOSE: This rule sets requirements for the maintenance of ongoing controlled substance records.

(1) Every registrant required to keep records shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported or otherwise disposed of by him/her.

(2) Separate records shall be maintained by a registrant for each registered location except as provided in 19 CSR 30-1.041(2). In the event controlled substances are in the possession or under the control of a registrant at a location for which s/he is not registered, the substance shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.

(3) Separate records shall be maintained by a registrant for each independent activity for which s/he is registered.

(4) In recording dates of receipt, importation, distribution, exportation or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (for example, invoices or packing slips).

(5) Records must be provided to the Department of Health within three working days upon request.

AUTHORITY: sections 195.050 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.050, RSMo 1939, amended 1971, 1989 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.046 Records for Manufacturers, Distributors, Importers and Exporters

PURPOSE: This rule sets requirements for record keeping by manufacturers, distributors, importers and exporters of controlled substances.

(1) Records for Manufacturers. Each registered manufacturer shall maintain records with the following information:

(A) For each controlled substance in bulk form to be used in or capable of use in or being used in the manufacture of the same or other controlled or noncontrolled substances in finished form –

1. The name of the substance;

2. The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

3. The quantity received from other persons including the date and quantity of each receipt and the name, address

and registration number of the other person from whom the substance was received;

4. The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him/her, including the date, quantity and import permit or declaration number for each importation;

5. The quantity used to manufacture the same substance in finished form including the date and batch or other identifying number of each manufacture; the quantity used in the manufacture; the finished form (for example, ten milligram (10 mg) tablets or ten milligram (10 mg) concentration per fluid ounce or milliliter); the number of units of finished form manufactured; the quantity used in quality control; the quantity lost during manufacturing and the causes for the loss, if known; the total quantity of the substance contained in the finished form; the theoretical and actual yields and other information as is necessary to account for all controlled substances used in the manufacturing process;

6. The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in paragraph (1)(A)5. of this rule;

7. The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address and registration number of each person to whom a distribution was made;

8. The quantity exported directly by the registrant, including the date, quantity and export permit or declaration number of each exportation;

9. The quantity distributed or disposed of in any other manner by the registrant (for example, distribution of complimentary samples or by destruction) including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity distributed or disposed;

(B) For each controlled substance in finished form –

1. The name of the substance;

2. Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, 100 tablet bottle or three milliliter (3 ml) vial);

3. The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required in paragraph (1)(A)5. of this rule;

4. The number of units of finished forms, commercial containers, or both, received from other persons, including the date of and number of units, commercial containers, or both, in each receipt and the name, address and registration number of the person from whom the units were received;

5. The number of units of finished form, commercial containers, or both, imported directly by the registrant, including the date of and the number of units, commercial containers, or both, in each importation;

6. The number of units, commercial containers, or both, manufactured by the registrant from units in finished form received from others or imported including: the date and batch or other identifying number of each manufacture; the operation performed (for example, repackaging or relabeling); the number of units of finished form used in the manufacture, the number manufactured and the number lost during the manufacture, with the causes for these losses, if known, and other information as is necessary to account for all controlled substances used in the manufacturing process;

7. The number of commercial containers distributed to other persons including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed;

8. The number of commercial containers exported directly by the registrant, including the date, number of containers and export permit or declaration number for each exportation;

9. The number of units of finished forms, commercial containers, or both, distributed or disposed of in any other manner by the registrant (for example, by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity in finished form distributed or disposed.

(2) Records for Distributors. Each registered distributor shall maintain records with the following information for each controlled substance:

(A) The name of the substance;

(B) Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, 100 tablet bottle or three milliliter (3 ml) vial);

(C) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received;

(D) The number of commercial containers of each finished form imported directly by the registrant including the date of and the number of containers in each importation;

(E) The number of commercial containers of each finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address and registration number of the person to whom the containers were distributed;

(F) The number of commercial containers of the finished form exported directly by the registrant, including the date of and the number of containers in each exportation;

(G) The number of units or volume of finished forms, commercial containers, or both, distributed or disposed of in any other manner by the registrant (for example, by distribution as complimentary samples) including the date and manner of distribution or disposal, the name, address and registration number of the person to whom distributed and the quantity of the substance in finished form distributed or disposed.

(3) Records for Importers. Each registered importer shall maintain records with the following information for each controlled substance:

(A) The name of the substance;

(B) The quantity (or number of units or volume in finished form) imported, including the date, quantity (or number of units or volume) and import permit or declaration number for each importation;

(C) The quantity (or number of units or volume in finished form) distributed to other persons, including the date, quantity (or number of units or volume) of each distribution and the name, address and registration number of each person to whom a distribution was made;

(D) The quantity disposed of in any other manner by the registrant except quantities used in manufacturing by an importer under a registration as a manufacture, which

quantities are to be recorded, including the date and manner of disposal and the quantity disposed.

(4) Records for Exporters. Each registered exporter shall maintain records with the following information for each controlled substance:

(A) The name of the substance;

(B) The quantity (or number of units or volume in finished form) received from other persons, including the date and quantity (or number of units or volume) of each receipt and the name, address and registration number of each person from whom the substance was received;

(C) The quantity (or number of units or volume in finished form) exported, including the date, quantity (or number of units or volume) and the export permit or declaration number for each exportation, but excluding all quantities (and numbers of units and volumes) manufactured by an exporter under a registration as a manufacture, which quantities (and numbers of units and volumes) are to be recorded;

(D) The quantity disposed of in any other manner by the registrant including the date and manner of disposal and the quantity disposed.

AUTHORITY: sections 195.050 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.050, RSMo 1939, amended 1971, 1989 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.048 Records for Practitioners and Researchers

PURPOSE: This rule sets requirements for record keeping for practitioners and researchers. It also sets requirements for the use of facsimile and electronic prescriptions.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Each individual practitioner, institutional practitioner, and pharmacy shall maintain records with the following information for each controlled substance received, maintained, dispensed, or disposed:

(A) The name of the substance;

(B) Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, one hundred (100) tablet bottle or three milliliter (3 ml) vial);

(C) The number of commercial containers of each finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received;

(D) The number of units or volume of the finished form dispensed including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance; and

(E) The number of units or volume of the finished forms, commercial containers, or both, disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.

(2) Each individual practitioner shall maintain a record of the date, full name and address of the patient, the drug name, strength, dosage form, and quantity for all controlled substances prescribed or administered. This record may be maintained in the patient's medical record. When the controlled substance record is maintained in the patient's medical record and the practitioner is not the custodian of the medical record, the practitioner shall make the controlled substance record available as required in 19 CSR 30-1.041 and 19 CSR 30-1.044.

(3) Individual practitioners shall maintain the records listed in subsections (1)(A)–(E) of this rule separately from patient medical records.

(4) A registrant who transfers a controlled substance to or receives a controlled substance from another registrant shall maintain a written record of the transfer which contains the following information: the date of transfer, drug name, strength, dosage form, quantity, name, address and registration number of the transferring registrant, and the name, address and registration number of the receiving registrant.

(5) Drug Enforcement Administration official order forms shall be used for transfers of Schedule II controlled substances.

(6) A prescription may not be issued for an individual practitioner to obtain controlled substances for dispensing or administering to patients.

(7) Prescriptions which are transmitted by facsimile to a pharmacy for dispensing shall include the telephone number of the facsimile machine or computer from which it is sent and the date and time of transmission. Immediately after a Schedule III, IV or V prescription or a Schedule II prescription for a long-term care facility patient or hospice patient or for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion is transmitted to a pharmacy by facsimile equipment, the practitioner or the practitioner's agent shall sign and date the face of the prescription. The prescriptions shall be maintained in chronological order separately from patient medical records in a manner so each prescription is readily retrievable for inspection at the transmitting practitioner's office. In the event the facsimile is transmitted from a long-term care facility or hospital, the prescription shall be maintained at the long-term care facility or hospital in chronological order separately from the patient medical records in a manner so each prescription is readily retrievable, or maintained in the patient medical records.

(8) Any pharmacy receiving a controlled substance prescription transmitted by facsimile equipment shall maintain the facsimile copy of the prescription along with the date and time of transmission and the telephone number of the facsimile machine from which it originated, as a part of its original prescription records.

(9) The creation, signature, transmission, and processing of

controlled substance prescriptions electronically and record keeping for electronic controlled substance prescriptions shall meet the requirements of 21 CFR Parts 1300 to end, which are hereby incorporated by reference in this rule as published April 1, 2014, by the Office of Federal Register, National Archives and Records Administration, and are made available to the public by the U.S. Government Printing Office, 732 N. Capitol Street NW, Washington, D.C. 20401, or at www.gpoaccess.gov/cfr/. This rule does not incorporate any subsequent amendments or additions.

AUTHORITY: section 195.050, RSMo 2000, and section 195.195, RSMo Supp. 2014. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 29, 2015, effective July 30, 2015.*

**Original authority: 195.050, RSMo 1939, amended 1971, 1989 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.050 Records for Chemical Analysts

PURPOSE: This rule sets requirements for record keeping for chemical analyst registrants.

(1) Each person registered to conduct chemical analysis with controlled substances shall maintain records with the following information (to the extent known and reasonably ascertainable by him/her) for each controlled substance:

(A) The name of the substance;

(B) The form(s) in which the substance is received, imported or manufactured by the registrant (for example, powder, granulation, tablet, capsule or solution) and the concentration of the substance in that form (for example, Chemically Pure (CP), United States Pharmacopeia (USP), National Formulary (NF), ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per milliliter);

(C) The total number of the forms received, imported or manufactured (for example 100 tablets, 30 one milliliter (1 ml) vials or ten grams (10 g) powder), including the date and quantity of each receipt, importation or manufacture and the name, address and registration number, if any, of the person from whom the substance was received; and

(D) The quantity distributed, exported or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation or destruction and the name, address and registration number, if any, of each person to whom the substance was distributed or exported.

(2) Order forms, import and export permits, import invoices and export declarations relating to controlled substances shall be maintained separately from all other records of the registrant.

(3) Records of controlled substances used in chemical analysis or other laboratory work are not required.

(4) Records relating to known or suspected controlled substances received as samples for analysis are not required under section (1) of this rule.

AUTHORITY: sections 195.050 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.050, RSMo 1939, amended 1971, 1989 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.052 Records for Long-Term Care Facilities (LTCF)

PURPOSE: This rule sets requirements for record keeping by long-term care facility registrants.

(1) Long-term care facilities (LTCFs) and their suppliers shall maintain written records of transfers of controlled substances from the supplier to the LTCF emergency kit.

(2) The records shall include the date of transfer; the name of each controlled substance, the strength, dosage form and quantity; the name, address and controlled substance registration number of the supplier and the name, address and controlled substance registration number of the LTCF. Federal Drug Enforcement Administration (DEA) official order forms shall not be used to record transfers of controlled substances to LTCF emergency kits.

(3) No physician's order or prescription shall be used for initial stocking or replacement of controlled substances in the emergency kit. Controlled substances contained in the kit shall be obtained from a pharmacy, hospital or practitioner who holds a controlled substances registration.

(4) The administration and medical staff of the LTCF, in conjunction with the primary supplier, shall designate in written protocols and procedures who may have access to the emergency kit, who may administer controlled substances from the emergency kit and under what circumstances and a list of the controlled substances it intends to maintain in the emergency kit. These protocols and procedures shall be subject to review and approval by the Department of Health. Only those individuals designated in the LTCF's written policies and procedures shall have access to or administer controlled substances from the emergency kit.

(5) Each administration of controlled substances from the emergency kit shall be based upon a practitioner's order and shall be recorded in an administration record separate from the patient's medical record. This administration record shall include: the date, patient's name, drug name, drug strength, dosage, ordering practitioner's name and name of the person administering the controlled substance.

AUTHORITY: sections 195.050 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.050, RSMo 1939, amended 1971, 1989 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.060 Determining Lawful Prescribing, Dispensing and Administering of Controlled Substances

PURPOSE: This rule defines the statutory and regulatory basis for determining what is lawful prescribing, dispensing and administering of controlled substances.

When determining if controlled substances are being lawfully prescribed, dispensed and administered by practitioners, the Department of Health shall enforce Chapter 195, RSMo, the Department of Health rules in 19 CSR 30 pertaining to controlled substances, and the federal Controlled Substances Act 21 U.S.C. 801–966, and its regulations, 21 CFR 1300–1399. In determining lawful prescribing, dispensing and administering of controlled substances, the Department of Health also shall

consider the provisions of Chapters 330, 332, 334, 335, 336, 338 and 340, RSMo, the rules in 4 CSR 110, 4 CSR 150, 4 CSR 200, 4 CSR 210, 4 CSR 220, 4 CSR 230 and 4 CSR 270, and protocols relating to the respective practitioners established and on file at the respective licensing boards.

AUTHORITY: sections 195.030, RSMo Supp. 1999 and 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov 30, 2000.*

**Original authority: 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1999 and 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.062 Transmission of Prescriptions

PURPOSE: This rule sets requirements governing the transmission of prescription information.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) Prescriptions in Schedule II. A pharmacist may dispense a controlled substance in Schedule II only under a written prescription signed by the practitioner, except as provided in section 195.060.3, RSMo. A prescription for a Schedule II controlled substance may be transmitted from the prescribing practitioner to a pharmacy by facsimile equipment, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except that –

(A) A prescription written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile which has been reduced to writing shall serve as, and shall be maintained in the same manner, as an original written prescription.

(B) A prescription written for a Schedule II substance for a resident of a long-term care facility may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile which has been reduced to writing shall serve as, and shall be maintained in the same manner, as an original written prescription.

(C) A prescription written for a Schedule II substance for a patient of a hospice may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient. The facsimile which has been reduced to writing shall serve as, and shall be maintained in the same manner, as an original written prescription.

(2) Prescriptions in Schedule III, IV, or V. A pharmacist may dispense directly a controlled substance in Schedule III, IV, or V only under a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or his/her authorized agent or under an oral prescription made by an individual practitioner whether communicated by the practitioner or his/her authorized agent by the authorizing practitioner or the practitioner's agent to the pharmacy. All oral prescriptions shall be promptly reduced to writing by the pharmacist containing all information required in section 195.060, RSMo, except for the signature of the practitioner.

(3) Written Prescriptions. All written controlled substance prescriptions shall be signed by the prescribing practitioner on the date prescribed. No controlled substance prescription shall be signed prior to the actual date it is issued.

(4) Prescriptions Transmitted by Electronic Computer Transmission. A pharmacist may dispense a controlled substance in Schedule II, III, IV, or V under a prescription transmitted from the prescribing practitioner to a pharmacy by electronic computer transmission provided that the prescription and its transmission complies with federal law regarding electronic prescriptions as found in the Code of Federal Regulations, Title 21 Part 1300 to end. The federal rules regarding electronic prescriptions are hereby incorporated by reference in this rule as published April 1, 2014, by the Office of Federal Register, National Archives and Records Administration, and are made available to the public by the U.S. Government Printing Office, 732 N. Capitol Street NW, Washington, D.C. 20401, or at www.gpoaccess.gov/cfr/. This rule does not incorporate any subsequent amendments or additions.

AUTHORITY: section 195.195, RSMo Supp. 2014. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 29, 2015, effective July 30, 2015.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.064 Partial Filling of Controlled Substance Prescriptions

PURPOSE: This rule sets requirements for the partial filling of Schedule II prescriptions.

(1) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription, and s/he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription), or in the electronic record. The remaining portion of the prescription may be filled within seventy-two (72) hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the seventy-two- (72-) hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.

(2) The partial filling of a prescription for controlled substances listed in Schedules II, III, IV, or V is permissible, provided that –

(A) Partial filling may occur at the request of a patient or it may be directed by the prescriber, unless the prescription is written for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness, in which case the pharmacist must record on the prescription whether the patient is "terminally ill" or "LTCF patient.";

(B) Each partial dispensing is recorded in the same manner as a refilling would be;

(C) With each partial dispensing, the pharmacy must document the date and quantity dispensed on the original prescription record or their electronic computer applications, provided that the electronic system meets all of the federal requirements for handling of electronic prescriptions for controlled substances, including the ability to retrieve the information pertaining to partially filled controlled substances;

(D) The total quantity dispensed in all partial fillings cannot exceed the total quantity prescribed;

(E) No dispensing occurs –

1. For controlled substances listed in Schedule II, after sixty (60) days after the date on which the original prescription was issued; and

2. For controlled substances listed in Schedules III and IV after six (6) months after the date on which the original prescription was issued;

(F) A partial dispensing is not considered a "refill" if the patient does not receive the full authorized amount at one time; and

(G) The prescription was written and filled in accordance with all other applicable laws and regulations.

AUTHORITY: section 195.080, RSMo Supp. 2020, and section 195.195, RSMo 2016. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed Jan. 29, 2015, effective July 30, 2015. Emergency amendment filed Sept. 17, 2018, effective Sept. 27, 2018, expired March 25, 2019. Amended: Filed Sept. 17, 2018, effective March 30, 2019. Amended: Filed Oct. 30, 2020, effective April 30, 2021.*

**Original authority: 195.080, RSMo 1939, 1965, 1971, 1987, 1989, 1997, 2005, 2010, 2012, 2014, 2018, 2019 and 195.195, RSMo 1957, amended 1971, 1989, 1993, 2014.*

19 CSR 30-1.066 Dispensing by Individual Practitioners

PURPOSE: This rule sets requirements for individual practitioners who dispense controlled substances.

(1) An individual practitioner who dispenses controlled substances shall –

(A) Provide direct supervision to employees or agents who assist in the administering or dispensing of controlled substances. Controlled substances shall not be dispensed from an individual practitioner's inventory unless a practitioner is physically in the registered location except pursuant to the provisions of section (2) of this rule;

(B) Package all controlled substances dispensed from an individual practitioner's inventory in compliance with the Poison Prevention Packaging Act of 1970, 15 U.S.C. 1471–1476;

(C) Permanently affix a label to the exterior of the drug container which includes: the date, the name and address of the dispensing practitioner, the name of the patient, directions for use, and the exact name and strength of the drug dispensed for all controlled substances dispensed;

(D) Dispense only to individuals with whom the practitioner has established and documented a practitioner/patient relationship. An individual practitioner shall not dispense under the order of another practitioner not practicing at that location.

(2) Mid-level practitioners shall not independently purchase, stock, administer, and dispense controlled substances. Controlled substances may be administered or dispensed from an individual practitioner's inventory by a mid-level practitioner with whom he or she has entered into an agreement pursuant to Chapter 334, RSMo, when the practitioner is not present at the registered location.

AUTHORITY: section 195.195, RSMo 2000. Original rule filed April 14, 2000, effective Nov. 30, 2000. Amended: Filed April 29, 2011, effective Nov. 30, 2011.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.068 Administering In Emergency Rooms

PURPOSE: This rule sets requirements for administering controlled substances in hospital emergency rooms.

(1) Controlled substances may be administered to a hospital emergency room patient under a verbal order of a registered practitioner who is not physically present if –

(A) The order is for a legitimate medical purpose and the practitioner who orders the administration of a controlled substance is acting in the usual course of his/her medical practice, after sufficient examination and establishment of a practitioner/patient relationship;

(B) The practitioner who orders the administration of a controlled substance is a medical staff member of the hospital;

(C) The administration of a controlled substance is documented in a formal medical record for the patient;

(D) The patient is assessed in the hospital by a practitioner, when available, or a registered nurse. If the patient is not assessed by a practitioner in the hospital, a registered nurse shall assess the patient and confirm and document in the patient's medical record the existence of a preestablished practitioner/patient relationship with the practitioner who ordered administration of a controlled substance;

(E) The order is written in the patient's medical record and is authenticated by the ordering practitioner within a time frame and manner as defined by the medical staff in cooperation with nursing and administration. This policy shall be included in the hospital's written policies and procedures.

AUTHORITY: section 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.070 Emergency Dispensing of Schedule II Substances

PURPOSE: This rule provides for the prescribing and dispensing of Schedule II drugs in an emergency situation.

(1) In the case of a bona fide emergency situation, as defined by the Department of Health, a pharmacist may dispense a Schedule II controlled substance upon receiving oral authorization of a prescribing practitioner; provided, that –

(A) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a written prescription;

(B) The prescription immediately shall be reduced to writing by the pharmacist and shall contain all information, except for the prescribing practitioner's signature;

(C) If the prescribing practitioner is not known to the pharmacist, s/he must make reasonable effort to determine that the oral authorization came from a practitioner, by

verifying his/her phone number against that listed in the directory and other good faith efforts to insure his/her identity;

(D) Within seven days after authorizing an emergency oral prescription, the prescribing practitioner must cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. The prescription shall have written on its face authorization for emergency dispensing. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the seven-day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the Department of Health if the prescribing practitioner fails to deliver a written prescription to him/her; failure of the pharmacist to do so shall void the authority conferred by this section to dispense without a written prescription of a prescribing practitioner.

(2) Definition of Emergency Situation. For the purpose of authorizing an oral prescription of a controlled substance listed in Schedule II of the controlled substances law (sections 195.010–195.320, RSMo), the term emergency situation means those situations in which the prescribing practitioner determines that –

(A) Immediate administration of a controlled substance is necessary for proper treatment of the intended ultimate user;

(B) No appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II;

(C) It is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance prior to the dispensing.

AUTHORITY: section 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.072 Dispensing of Schedule V Substances

PURPOSE: This rule provides for the prescribing, administering and dispensing of Schedule V drugs.

(1) A pharmacist may dispense directly a controlled substance listed in Schedule V pursuant to a prescription. A prescription for a controlled substance listed in Schedule V may be refilled only as expressly authorized by the prescribing individual practitioner. If this authorization is not given, the prescription may not be refilled. A pharmacist dispensing those substances pursuant to a prescription shall label the substance and file the prescription.

(2) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule V in the course of his/her professional practice without a prescription.

(3) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule V only pursuant to a written prescription signed by the prescribing individual practitioner or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required except for the signature of the prescribing individual practitioner) or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

AUTHORITY: section 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.074 Dispensing Without a Prescription

PURPOSE: This rule provides for dispensing Schedule V controlled substances without a prescription in certain situations.

(1) Definitions. For the purposes of this rule, the following terms shall apply:

(A) "Dispenser" means a pharmacist, intern pharmacist, or registered pharmacy technician who sells, dispenses, or otherwise provides methamphetamine precursor products to purchasers.

(B)"Methamphetamine precursor products" means both Schedule V pseudoephedrine products and any other drug product containing any detectable amount of ephedrine, pseudoephedrine, or phenylpropanolamine, including the salts or optical isomers or salts of optical isomers or ephedrine, its salts or optical isomers, or salts of optical isomers of ephedrine, pseudoephedrine, or phenylpropanolamine.

(C) "Valid photo identification" means a photo identification that is issued by a state or the federal government or a document that, with respect to identification, is considered acceptable and showing the date of birth of the person, including forms of identification acceptable under federal regulations 8 CFR 274a.2(b)(1)(v)(A) and (B).

(2) Dispensing Without a Prescription. A controlled substance listed in Schedule V which is not a prescription drug under the federal Food, Drug and Cosmetic Act, and is not a methamphetamine precursor product, may be dispensed by a pharmacist without a prescription to a purchaser at retail; provided, that –

(A) Dispensing is made only by a pharmacist and not by a non-pharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his/her professional and legal responsibilities, the actual cash transaction, credit transaction, or delivery may be completed by a non-pharmacist); and

(B) Dispensing, sale, distribution, or otherwise providing is limited to not more than two hundred forty cubic centimeters (240 cc) or eight ounces (8 oz.) of any controlled substance containing opium, nor more than one hundred twenty cubic centimeters (120 cc) or four ounces (4 oz.) of any other controlled substance, nor more than forty-eight (48) dosage units of any controlled substance containing opium, nor more than twenty-four (24) dosage units of any other controlled substance may be dispensed at retail to the same purchaser in any given forty-eight (48)-hour period.

(3) Methamphetamine precursor products may be sold, dispensed, distributed, or otherwise provided only as follows:

(A) Products that are designated Schedule V controlled substances which contain any detectable amount of pseudoephedrine, ephedrine, phenylpropanolamine, their salts or optical isomers, or salts of their optical isomers may be sold, distributed, or otherwise provided only by a pharmacist or pharmacy ancillary personnel as authorized by the Missouri

State Board of Pharmacy;

(B) Dispensers of methamphetamine precursor products shall exercise reasonable care in assuring that the purchaser has not exceeded the three and six-tenths- (3.6-) gram limit per day or the seven and two-tenths- (7.2-) gram limit per thirty- (30-) day period. Within any twelve- (12-) month period, no person shall sell, dispense, or otherwise provide the same individual, and no person shall purchase, receive, or otherwise acquire more than forty-three and two-tenths- (43.2-) grams, without regard to the number of transactions;

(C) Dispensers shall utilize the real-time electronic pseudoephedrine tracking system established and maintained by the Missouri Department of Health and Senior Services (DHSS). No prescription shall be required for the sale or dispensing of these drug products; however, prescribers and patients may voluntarily choose to use a prescription by voluntary choice when deemed appropriate by the prescriber in the course of his or her professional practice;

(D) Methamphetamine precursor products regulated by Missouri law as controlled substances shall only be sold to customers eighteen (18) years of age or older who present a valid photo identification;

(E) Any dispenser who sells, dispenses, or otherwise provides any methamphetamine precursor product shall submit the following information to the DHSS electronic database at the time of purchase:

1. Date and time of transaction;

2. Pharmacy identification information, including:

A. National Council for Prescription Drug Programs identification number; or

B. National Association of Boards of Pharmacy identification number; or

C. Vendor assigned site and/or pharmacy identifier;

3. Purchaser information, including the following fields:

A. Purchaser's given or first name;

B. Purchaser's middle name (if any);

C. Purchaser's surname or last name;

D. The purchaser's full name shall be entered into the database without the use of initials or nicknames;

E. Purchaser's date of birth; and

F. Purchaser's address, including number, street, city, state, and zip code;

4. Identification of the form of valid photo identification presented by the purchaser; including issuing agency of the photo identification and identification number appearing on the photo identification;

5. Purchaser's signature;

6. Dispenser identification, including:

A. The name of the individual performing the transaction; or

B. The initials of the individual performing the transaction;

7. Transaction number, assigned by the database provider/vendor;

8. Purchase transaction information, including the following:

A. Product Universal Product Code (UPC);

B. Product National Drug Code (NDC) (optional);

C. Unique product description; and

D. Purchase quantity, in grams as –

(I) Product grams per box and number of boxes in transaction;

(II) Product grams per dosage form such as tablet, capsule, or milliliter, and number of dosages per transaction; or

(III) Other mechanism identified by the database provider/vendor; and

9. Form of pseudoephedrine in a manner defined by the database provider/vendor, including but not limited to:

A. Tablet;

B. Capsule;

C. Liquid-filled gelcap; or

D. Liquid;

(F) Purchaser information provided and entered into the DHSS electronic database shall be the same as that on the presented identification. Full names shall be used and not merely initials or a nickname;

(G) If the DHSS electronic database is not available at the time of the sale of the methamphetamine precursor product, the information to be provided in subsection (3)(E) above shall be recorded manually and entered into the DHSS electronic database as soon as practicable after the system is back online, as specified in subsection (3)(I). Signatures shall be captured on paper and then may be scanned to the database;

(H) Every dispenser who sells, dispenses or otherwise provides any methamphetamine precursor product shall maintain a bound logbook in addition to the electronic database system. The logbook shall be used for documenting a clear audit trail of any alterations, changes, or deletions to the original transaction record, and sales that occurred during system failures, including date and time of entry into the database, justification, and resultant contacts with law enforcement because the override button was used;

(I) In the event that the DHSS electronic database is unavailable for five (5) minutes or more due to a failure on the DHSS network or because of a failure attributable to systems other than the DHSS, the dispenser may continue with the transaction until the system is available. All information required to be captured with each transaction shall be retained and documented. The information may be entered into the database where it may be held pending until the system comes back on line, or all of the required information for transactions occurring during the time the DHSS electronic database is unavailable must be recorded manually and entered into the DHSS electronic database by the registrant as soon as is practicable, but within no more than forty-eight (48) hours following the resumption of operability. Documentation shall also identify the reason for the late entry into the DHSS electronic database;

(J) At least once each month, the pharmacist-in-charge shall review the logbook of changes and the changes captured by the database to see what changes and alterations pharmacy employees have entered regarding sales of methamphetamine precursors. The date and time that the pharmacist-in-charge conducts this monthly review shall be documented in the bound logbook maintained by the pharmacy in addition to the electronic system;

(K) Documentation in the bound logbook shall be maintained in a readily retrievable manner for two (2) years from the date of the transaction and available for inspection and copying by authorized DHSS employees and law enforcement;

(L) Denials of Sales and Dispensings.

1. Except as provided in subsection (D) of this section, if an individual attempts to purchase a methamphetamine precursor product in violation of the three and six-tenths (3.6) gram per day or seven and two-tenths (7.2) gram per month quantity restrictions or age restriction established by sections 195.017 and 195.417, RSMo, the dispenser shall refuse to make the sale. The purchaser must be at least eighteen (18) years of age.

2. Sales of methamphetamine precursor products shall be denied to purchasers who are not able to produce a

valid government issued identification card with the required information displayed on it.

3. In the event that the dispenser perceives that refusal of the purchase may place him or her in imminent physical harm, then the dispenser may use the database safety override function to proceed with the transaction, provided that –

A. When jeopardy is no longer perceived, the dispenser shall immediately contact local law enforcement to report the purchase; and

B. The dispenser shall document in their manual log, the circumstance, the individual contacted at the local law enforcement agency, and the date and time of that contact;

(M) Pharmacy Employees. Employees in a pharmacy shall be assigned individual personal passwords to identify their own transactions in the database.

1. Pharmacy employees shall only use their own passwords for their own transactions and shall not dispense or make a sale under the password of another person.

2. The database computer shall not be left on and unattended so that another person can use the previous user's password. Users shall close out their personal access when their activities are completed.

3. The pharmacist-in-charge shall be responsible for insuring pharmacy employees have adequate password privileges. The pharmacist-in-charge shall insure that new employees have their own personal passwords and also insure that ex-employees have their passwords removed from the system;

(N) Access to Database by Law Enforcement and Regulatory Agencies.

1. Access to the database and controlled substance records shall be made available to those agencies with authority under Chapter 195 and Chapter 338, RSMo.

2. Law enforcement agencies and regulatory agencies shall only have the ability to read and review and shall not be able to enter data or change records.

3. It shall be the responsibility of each agency's administrator, chief, sheriff, or other chief executive officer to insure –

A. Only authorized employees have access to the database;

B. Employees only use their own passwords and passwords are not shared;

C. Each employee adheres to all state and federal laws regarding confidentiality; and

D. As employees change, that new passwords are assigned to new employees and passwords of ex-employees or transferred employees are removed. The chief, sheriff, or chief executive officer of the law enforcement or regulatory agency shall notify the DHSS in writing when an employee's access is to be added or removed; and

(O) Method for Enforcement Agencies to Gain or Alter Access to the Database.

1. Requests submitted to the DHSS to add or remove an employee from access to the database shall –

A. Be submitted in writing on the agency's letterhead;

B. State whether this is a request for an employee to be granted access to the database or a request to remove an employee's access;

C. Provide the employee's full name and title;

D. Provide the employee's Missouri POST certification number if the employee is a sworn law enforcement officer; and

E. Be signed by the chief, sheriff, or chief executive officer of the requesting agency.

2. Multiple requests for multiple employees and actions may be submitted on one (1) letter.

3. The DHSS shall notify the provider of the database in writing of persons who are given access or have access removed.

4. The DHSS may restrict access to the database to a limited number of people in each agency, depending on the size of the agency, their locations, and number of sworn officers engaged in the actual enforcement of controlled substance laws.

AUTHORITY: section 195.017, RSMo Supp. 2020, and sections 195.030, 195.050, 195.195, and 195.417, RSMo 2016. Original rule filed April 14, 2000, effective Nov. 30, 2000. Emergency amendment filed Aug. 18, 2005, effective Aug. 28, 2005, expired Feb. 23, 2006. Amended: Filed Sept. 1, 2005, effective Feb. 28, 2006. Emergency amendment filed July 9, 2010, effective Sept. 28, 2010, expired March 26, 2011. Amended: Filed June 29, 2010, effective Jan. 30, 2011. Amended: Filed Oct. 30, 2020, effective April 30, 2021.*

**Original authority: 195.017, RSMo 1971, amended 1987, 1989, 1994, 1996, 1997, 1998, 2001, 2005, 2006, 2008, 2010, 2011, 2014, 2018, 2020; 195.030, RSMo 1939, amended 1971, 1989, 1993, 1995, 1997, 1999, 2014; 195.050, RSMo 1939, amended 1971, 1989, 2014; 195.195, RSMo 1957, amended 1971, 1989, 1993, 2014; and 195.417, RSMo 2001, amended 2003, 2005, 2008, 2014, 2020.*

19 CSR 30-1.076 Emergency Distribution by a Pharmacy

PURPOSE: This rule provides for dispensing of controlled substances by a pharmacy in emergency situations.

(1) An emergency means a situation where a quantity of a controlled substance must be dispensed by a pharmacy to a patient who does not have an alternative source for that substance reasonably available to him/her and the pharmacy cannot obtain that substance through its normal distribution channels within the time required to meet the immediate needs of the patient for that substance. In the event of an emergency, a pharmacy may distribute (without being registered as a distributor) a controlled substance in Schedule III, IV or V to a second pharmacy in order for that pharmacy to dispense the substance; provided, that –

(A) The amount distributed does not exceed the amount required by the second pharmacy for his/her immediate dispensing;

(B) The distribution is recorded as being dispensed by the first pharmacy and the second pharmacy records the substance as being received. Each pharmacy will retain a signed receipt of the distribution;

(C) The second pharmacy is registered to dispense the controlled substance to be distributed to him/her;

(D) If the substance is a Schedule II controlled substance, the official order form designated by the federal Drug Enforcement Administration must be used to document the transfer.

AUTHORITY: section 195.195, RSMo 1994. Original rule filed April 14, 2000, effective Nov. 30, 2000.*

**Original authority: 195.195, RSMo 1957, amended 1971, 1989, 1993.*

19 CSR 30-1.078 Disposing of Unwanted Controlled Substances

PURPOSE: This rule establishes procedures for disposing of unwanted controlled substances.

(1) A registrant in possession of any controlled substance(s) and desiring or required to dispose of such substance(s) shall:

(A) Return the controlled substances to the original supplier;

(B) Transfer the controlled substances to a distributor authorized to accept controlled substances for the purpose of disposal;

(C) Retain a DEA Form 41 in compliance with federal regulations;

(D) Become an Authorized Collector of Controlled Substances. Registrants shall dispose of all unwanted controlled substances and keep records in accordance with federal regulations. Only manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that have modified their state and federal controlled substances registrations may possess a collection receptacle for medication disposal or participate in the DEA approved mail-back system;

(E) Contact the Bureau of Narcotics and Dangerous Drugs (BNDD), Department of Health and Senior Services for information pertaining to subsections (1)(A), (B), (C) or (D) of this rule.

(2) Destruction of controlled substances in patient care areas.

(A) Controlled substances that have been contaminated by patient contact are to be destroyed on site. An excess volume of a controlled substance which must be discarded from a dosage unit just prior to administration shall also be destroyed on site.

(B) Controlled substances that have not been contaminated by patient contact or are not excess volumes of a dosage unit shall not be destroyed on site unless the registrant maintains a DEA Form 41 in compliance with federal regulation. Unwanted controlled substances that have been expired, discontinued, or are otherwise unwanted shall be disposed of by methods listed previously in section (1) of this rule.

(C) In a patient care area of a hospital with an on-site pharmacy, unwanted controlled substances that have not been contaminated by patient contact shall be returned to the pharmacy for final disposal.

(D) The destruction of controlled substances shall be in such a manner that it renders the medication unrecoverable and beyond reclamation so that it cannot be diverted.

(E) The destruction and documentation of destruction shall be performed and completed by two (2) people. One of the people must be a licensed physician, nurse, pharmacist, intern pharmacist, or pharmacy technician, assistant physician, physician assistant, podiatrist, optometrist, dentist or veterinarian. The second person, the witness, is not required to be a licensed medical professional, but must be an employee of the registrant, unless in an EMS setting.

(F) The following shall be entered in the controlled substance administration record or a separate controlled substance destruction record when the controlled substance is destroyed in the patient care area: the date and hour of destruction, the drug name and strength, the amount destroyed, the reason for destruction, and the patient's name and room number if applicable, and the names or initials of the two (2) persons performing the destruction. The controlled substance administration and destruction records are to be retained for two (2) years and available for inspection by the Department of Health and Senior Services;

(3) In the event the registrant is a hospital, the following procedures are to be used for the destruction of controlled substance(s):

(A) When disposal of controlled substance(s) is in patient care areas –

1. Controlled substances which are contaminated by patient body fluids are to be destroyed by a physician, nurse, or a pharmacist in the presence of another hospital employee;

2. An excess volume of a controlled substance which must be discarded from a dosage unit just prior to use shall be destroyed by a nurse, pharmacist, or physician in the presence of another hospital employee;

3. The remaining contents of opened glass ampules of controlled substance(s) shall be destroyed by a nurse, pharmacist, or physician in the presence of another hospital employee;

4. Single units of single dose packages of controlled substance(s) which are contaminated other than by patient body fluids and are not an infectious hazard, have been removed from their original or security packaging, are partially used, or are otherwise rendered unsuitable for patient use shall be destroyed by a nurse, pharmacist, or physician in the presence of another hospital employee or returned to the pharmacy for destruction;

5. The following shall be entered in the controlled substance administration record or a separate controlled substance destruction record when the controlled substance(s) is destroyed in the patient care area: the date and hour of destruction, the drug name and strength, the amount destroyed, the reason for destruction, and the patient's name and room number. The nurse, pharmacist, or physician and the witnessing hospital employee shall sign the entry. The drug shall be destroyed so that it is beyond reclamation. The controlled substance administration or destruction records are to be retained for two (2) years and available for inspection by Department of Health investigators;

6. All other controlled substances which are not patient contaminated but which are to be disposed of shall be returned to the pharmacy for disposal;

(B) When disposal of controlled substance(s) is in the pharmacy –

1. Single units of controlled substance(s) which are contaminated other than by patient body fluids and are not an infectious hazard, have been removed from their original or security packaging, are partially used, or are otherwise rendered unsuitable for patient use shall be destroyed by a pharmacist in the presence of another hospital employee or held for later destruction;

2. All other controlled substances which are not patient contaminated but are to be disposed of shall be placed in a suitable container for storage and disposed of as described in section (1) of this rule.

(4) Collection Receptacle Boxes and Mail-Back Programs for Patients' Unwanted Controlled Substance Prescriptions.

(A) Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies are authorized to install collection receptacle boxes or participate in a DEA approved mail-back method to collect unwanted controlled substance prescription medications from patients. Registrants must comply with federal regulations regarding security and record keeping. Collection receptacles shall be used only for patients' unwanted medications and not for the expired or unwanted stock of a practitioner or facility.

(B) All facilities and locations with collection receptacle boxes and mail-back systems shall comply with federal regulations.

1. Patients' medications from long-term care facilities and narcotic treatment programs shall be placed in a receptacle within three (3) days of the expiration date on the medication; or upon a discontinuation of use authorized by a prescriber; or upon the death of a patient.

(C) Record keeping for collection receptacle boxes. Registrants or their employees shall not inventory the contents of the collection receptacle box. The collection receptacle box is to be opened by two (2) people; one shall be an employee of the pharmacy and the other may be an employee of the facility receiving pharmaceutical services. All registrants with collection receptacle boxes shall maintain a perpetual log that documents entry into the collection receptacle box, changing of liners, and transfers of drugs from the registrant to a reverse distributor. These logs shall be maintained on file at the registered location for inspection and shall document the date of entries into the collection receptacle box, the names of the employees entering the collection receptacle box, the reason for entering the receptacle, the serial number of a liner being removed, and the serial number of a new liner being installed. This log shall also be used to document the transfer of a liner from the registrant to a reverse distributor by documenting the date of transfer, serial number of the liner, names of the persons involved in the transfer, and the DEA number of the reverse distributor. The log shall also document when the pharmacy changes out the interior liner bags and document the serial number of the bag being removed and of the new bag being installed.

AUTHORITY: sections 195.050 and 195.195, RSMo Supp. 2018. Original rule filed April 14, 2000, effective Nov. 30, 2000. Emergency amendment filed Sept. 17, 2018, effective Sept. 27, 2018, expired March 25, 2019. Amended: Filed Sept. 17, 2018, effective March 30, 2019.*

**Original authority: 195.050, RSMo 1939, amended 1971, 1989, 2014 and 195.195, RSMo 1957, amended 1971, 1989, 1993, 2014.*

19 CSR 30-1.080 Electronic Prescribing Waiver

PURPOSE: This rule establishes the process for practitioners to obtain waivers to the electronic prescribing requirements established by section 195.550, RSMo.

(1) Practitioners required to utilize electronic prescribing pursuant to section 195.550, RSMo may request a waiver of this requirement from the Department of Health and Senior Services.

(A) Applications shall only be submitted by practitioners with active Missouri Controlled Substance Registrations. Applications shall not be submitted by a registrant's designee or representative.

(B) Applicants requesting a waiver shall submit an application for a waiver by sending their application to BNDDRxWaiver@health.mo.gov. A sample application may be found on the Department's website, www.health.mo.gov/safety/bndd.

(C) The application shall include:

1. Applicant's first and last name;
2. Applicant's licensure type;
3. Applicant's Missouri Controlled Substance Registration number;
4. Applicant's email address;
5. The Applicant shall indicate for which of the following reasons they are seeking a waiver:
   A. Economic hardship;
   B. Technological limitations; or
   C. Other exceptional circumstances;
6. The Applicant shall provide any additional details they consider necessary to support their waiver request;
7. The Applicant shall certify that the information included in their application is true and accurate; and
8. The Applicant shall sign and date the application. An electronic signature will satisfy this requirement.

(D) Waivers granted by the department shall be valid for one (1) year after the date on which they are issued.

(E) Waivers shall be kept on file at the practitioner's primary, principle practice location and available for review by the department.

AUTHORITY: section 195.550, RSMo Supp. 2020. Emergency rule filed Dec. 15, 2020, effective Dec. 31, 2020, expired June 28, 2021. Original rule filed Dec. 15, 2020, effective June 30, 2021.*

**Original authority: 195.550, RSMo 2019.*

19 CSR 30-2 (Hospital Pharmacy Rule)

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 20—Hospitals
19 CSR 30-20.011 Definitions Relating to Hospitals

PURPOSE: This rule defines terminology used throughout this chapter.

(1) Automated Dispensing System—An automated system that is used to dispense medication to patients pursuant to a patient-specific prescription or patient-specific medication order using an electronic verification system. An automated dispensing system does not include an automated system used for compounding medication or an automated filling system governed by 20 CSR 2220-2.950.

(2) Chemical Restraint—A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(3) Chief executive officer—The individual appointed by the governing body to act in its behalf in the overall management of the hospital.

(4) Chief operating officer—The individual appointed by the chief executive officer on behalf of the governing body or the individual who is responsible for the management of one (1) hospital in a multi-hospital organization under the direction of the chief executive officer of the organization.

(5) Compounding—The preparation, incorporation, mixing and packaging, or labeling of a drug or device as the result of a prescriber's prescription or prescription drug order based on the prescriber/patient/pharmacist relationship in the course of professional practice. Compounding may also be defined as the preparation, incorporation, mixing and packaging, or labeling of a drug or device, for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing purposes.

(6) Defined service area—The geographic area served by a defined group of hospitals and emergency services.

(7) Department—Missouri Department of Health and Senior Services.

(8) Diversion—Temporary closure of a hospital emergency department to ambulance traffic.

(A) Defined service area—The geographic area served by a defined group of hospitals and emergency services. In areas where there is a community-based emergency medical services diversion plan, the service area(s) defined as the catchment area by the plan will be the defined service area(s). In areas where there is not a community-based emergency medical services diversion plan, the defined service area will be a twenty- (20-) mile radius from a hospital.

(9) Hospital—

(A) A facility that provides inpatient care for medical or surgical patients, or both, and may include pediatric, obstetrical and newborn, psychiatric, or rehabilitation patients; and

(B) A facility that is devoted primarily for the diagnosis, treatment, or care for not less than twenty-four (24) consecutive hours in any week of three (3) or more nonrelated individuals suffering from illness, disease, injury, deformity, or other abnormal physical conditions, or devoted primarily to provide for not less than twenty-four (24) consecutive hours in any week medical or nursing care for three (3) or more nonrelated individuals and includes;

(C) Building(s)—

1. Constructed to hospital standards as outlined in 19 CSR 30-20.030; and
2. Identified on the hospital's license application as part of the facility; and

(D) The term "hospital" does not include convalescent, nursing, shelter, or boarding homes as defined in Chapter 198, RSMo.

(10) Immediate and serious threat—A situation in which a hospital's non-compliance with one (1) or more requirements established under the Hospital Licensing Law or section 197.005, RSMo has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident or patient. Unless the language or context clearly indicates otherwise, this definition is intended to have the same meaning, to the extent practicable, as the definition of immediate jeopardy in 42 CFR section 488.1 (2018). The Code of Federal Regulations is published by the U.S. Government and is available by calling toll-free (866) 512-1800 or going to https://bookstore.gpo.gov/. The address is: U.S. Government Publishing Office, U.S. Superintendent of Documents, Washington, DC 20402-0001. This rule does not incorporate later amendments or additions to 42 CFR section 488.1 (2018).

(11) Infectious waste—Waste capable of producing an infectious disease. Infectious waste shall include the following categories:

(A) Blood and blood products—All human blood and blood products including serum, plasma, and other components known or suspected to be contaminated with a transmissible agent;

(B) Microbiologic cultures and stocks of infectious agents and associated biological agents;

(C) Isolation wastes—Discarded waste contaminated with excretions, exudates, and secretions from patients with highly communicable diseases treated in isolation;

(D) Pathology wastes include human tissues and body parts that are removed during surgery and autopsy;

(E) Contaminated sharps—All discarded sharps including needles, syringes scalpels broken glass or other sharp items that have come in contact with potentially infectious material; and

(F) Animal waste—Discarded material originating from animals inoculated with infectious agents during research, production of biological or pharmaceutical testing.

(12) Inpatient—A person admitted into a hospital by a member of the medical staff for diagnosis, treatment, or care.

(13) Intern Pharmacist—An individual seeking to earn pharmacy practice experience in Missouri

(14) Licensed practitioner—Any individual who is licensed in Missouri or in another state and is qualified to practice a health care profession.

(15) Long-term care unit—A unit attached to or contained within a hospital that is operated as a skilled nursing unit.

(16) Operator—A person with—

(A) Ultimate responsibility for making and implementing decisions regarding the operation of the hospital; and

(B) Ultimate financial control of the operation of the hospital, including any management consultant or contracted entity who exercises control over the operation of the facility on a day-to-day basis.

(17) Patient—A person who presents to the hospital seeking diagnosis, treatment, or care.

(18) Pharmacist—An individual who is currently licensed under Chapter 338, RSMo, to practice pharmacy in the state of Missouri.

(19) Pharmacy technician—An individual who is currently registered under Chapter 338, RSMo, as a pharmacy technician in the state of Missouri.

(20) Physician—An individual who is currently licensed under Chapter 334, RSMo, to practice medicine in Missouri.

(21) Registered professional nurse—An individual who is licensed under Chapter 335, RSMo, to practice as a registered professional nurse in the State of Missouri.

(22) Repackage—To remove any drug from the original manufacturer's container and place the drug in a dispensing container for other than immediate dispensing to a patient.

(23) Resident—A person who by reason of aging, illness, disease, or physical or mental infirmity requires care and services furnished by a long-term care unit and who resides within the unit for care and treatment.

(24) Respiratory Care Practitioner—An individual who is licensed under Chapter 334, RSMo, to practice respiratory care in the State of Missouri.

(25) Root cause analysis—A process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event.

(26) Unit—A functional division or facility of the hospital.

(27) Unlicensed Assistive Personnel (UAP)—unlicensed health care personnel who provide direct patient care twenty-five percent (25%) or more of the time, under the delegation and supervision of a registered professional nurse. Individuals who provide a specific job function such as, but not limited to, phlebotomist, radiology technician, or patient transporter are
not included in this definition.

AUTHORITY: sections 192.006, 197.154, and 338.165, RSMo 2016, and sections 197.080 and 197.293, RSMo Supp. 2019. This rule was previously filed as 13 CSR 50-20.011. Original rule filed June 2, 1982, effective Nov. 11, 1982. Amended: Filed June 2, 1987, effective Sept. 11, 1987. Amended: Filed Aug. 16, 1988, effective Dec. 29, 1988. Amended: Filed Nov. 21, 1995, effective July 30, 1996. Amended: Filed Oct. 6, 1998, effective April 30, 1999. Amended: Filed June 28, 2001, effective Feb. 28, 2002. Amended: Filed Sept. 20, 2005, effective April 30, 2006. Amended: Filed March 20, 2019, effective Nov. 30, 2019.*

**Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995, 2017; 197.154, RSMo 2004; 197.293, RSMo 2000, amended 2004, 2017; and 338.165, RSMo 2014.*

19 CSR 30-20.100 Pharmacy Services and Medication Management

PURPOSE: This rule establishes the requirements for pharmacy services and medication management in a hospital to ensure optimal selection, safe use, and security of medications.

(1) There shall be evidence of the education, training, experience, and demonstrated competency for all duties assigned in the pharmacy technicians' personnel records.

(2) In addition to other authorized duties, a pharmacy technician may perform the following duties:

(A) Authenticate medication selected by another pharmacy technician when a pharmacist is present for purposes of distribution within the hospital for subsequent administration by hospital staff authorized to administer medication, provided the final product is verified by authorized hospital staff prior to administration. A pharmacy technician shall not be authorized to authenticate compounded medications or the repackaging activities of another pharmacy technician. In order to authenticate medication as described in this section, the pharmacy technician must—

1. Hold an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies;

2. Have an initial and annual documented assessment of competency; and

3. Have assisted in the practice of pharmacy as a registered or licensed pharmacy technician in the state of Missouri or another U.S. state or territory for a minimum of one (1) year; and

(B) Perform assigned duties under visual and auditory supervision of a pharmacist at a different site, including, technology assisted medication authentication. Documentation of electronic authentication shall be maintained at the dispensing site.

1. The pharmacy technician shall have a current certificate issued by a certification entity accredited by the National
Commission for Certifying Agencies.

2. The pharmacy technician shall have completed training and documented competency in the assigned responsibilities being performed remotely as attested by the director of pharmacy.

3. The director of pharmacy is responsible for developing and implementing standards to ensure adequate supervision of electronically supervised technicians.

(3) An intern pharmacist licensed by the Board of Pharmacy may also perform any activity authorized for pharmacy technicians pursuant to this rule.

(4) Persons involved in compounding, repackaging, dispensing, administration, and controlled substance disposal shall be identified and the records shall be retrievable. Retention time for records of bulk compounding, repackaging, administration, and all controlled substance transactions shall be a minimum of two (2) years. Retention time for records of dispensing and extemporaneous compounding, including sterile medications, shall be a minimum of six (6) months.

(5) All variances, discrepancies, inconsistencies, or

non-compliance involving controlled substances—including inventory, audits, security, record keeping, administration, and disposal—shall be reported to the director of pharmacy services for review and investigation.

(6) Patient medications may be received from an authorized provider. The medications shall—

(A) Be delivered directly to the pharmacy and not to a patient care area unless the pharmacist is not available;

(B) When a pharmacist is present, be identified, determined suitable for use and documented by the pharmacist. When a pharmacist is not present, be identified and documented by an authorized practitioner. Unused doses of medication shall be identified by the pharmacist when the pharmacist is present; and

(C) The pharmacy may compound, repackage, or re-label medications received from an outside provider, including prescriptions dispensed by a pharmacy, as necessary for proper distribution and administration. Records of compounding, repackaging, or relabeling of prescriptions dispensed by a pharmacy shall allow identification of the original prescription.

(7) Sample medications, if allowed, shall be received and distributed only by the pharmacy.

(8) Medications may be provided to patients for use outside the hospital, by persons other than the pharmacist.

(A) When the patient is a registered patient of the emergency department or is being discharged from the hospital—

1. Medications shall be provided according to the hospital's policies and procedures, including:

A. Circumstances when medications may be provided;

B. Practitioners authorized to order;

C. Specific medications;

D. Limited quantities;

E. Prepackaging and labeling by the pharmacist;

F. Final labeling to facilitate correct administration;

G. Delivery;

H. Counseling; and

I. A transaction record;

2. Medications shall be labeled with the date, patient's name, prescriber's name, name and address of the hospital, exact medication name and strength, instructions for use, and other pertinent information;

3. Medications may be provided only when prescription services from a pharmacy are not reasonably available. Reasonably available includes a pharmacist on duty in the hospital or a community pharmacy that is reasonably accessible to the patient;

4. The medication provided shall be limited to urgently needed treatment;

5. The quantity of medication provided shall be limited to the amount necessary until pharmacy services are available;

6. The provisions of paragraph (A)3. and paragraph (A)5. of this subsection shall not apply when the patient is being treated for an acute condition and it is believed that the immediate health and welfare of the patient and/or the community are in jeopardy. The quantity limit may be extended to provide single-course therapy; and

7. Final labeling, delivery, and counseling shall be performed by a pharmacist, the prescriber or a registered nurse

except that final labeling and delivery may be performed by an automated dispensing system.

(B) Automated dispensing systems may be used in accordance with all requirements of this section—

1.When the automated dispensing system is controlled by the prescriber it may be used only during times when no pharmacy services are reasonably available, except as allowed in paragraph (A)6. of this section; and

2. When the automated dispensing system is controlled by a pharmacy according to regulations of the Missouri Board of Pharmacy, including, but not limited to 20 CSR 2220-2.900.

(C) Medications in multidose containers that were administered to or used for the patient during the patient's hospital stay may be sent with the patient at discharge when so ordered by an authorized practitioner.

1. Examples of multidose medication containers include, but are not limited to, inhalers, ointments, creams, medications requiring the original container for dispensing, insulin pens, eye drops, ear drops, and infusions that are currently connected to the patient's infusion device.

2. Written instructions for use shall be provided by a pharmacist, prescriber, or registered nurse at the time of discharge.

3. Controlled substances shall not be sent with the patient, except that controlled substance infusions or continuous delivery systems currently connected to the patient may be sent as follows:

A. The medication is necessary for administration during transport of the patient; and

B. The quantity of controlled substance sent is documented in the patient's medical record by the person sending the medication.

(9) The director of pharmacy services or his/her pharmacist designee shall be an active member of the pharmacy and therapeutics committee or its equivalent, which shall advise the medical staff on all medication matters.

(10) Medications shall be ordered only by practitioners who have independent statutory authority to prescribe or who are authorized to order medications by their professional licensing agency as provided by state law. Authority to order medications may be granted to a non-physician licensed practitioner in accordance with state law.

(11) Medications in the possession of the patient at time of admission shall be given to the patient's representative unless there is an identified need to retain them.

(A) Medications that are not given to the patient's representative and that are not to be administered shall be documented, sealed, and stored in a locked area accessible only to individuals authorized to access medications.

(B) Controlled substances shall be security sealed and stored in a locked area accessible only to individuals authorized to administer controlled substances or to

authorized pharmacy personnel.

AUTHORITY: sections 192.006 and 338.165, RSMo 2016, and section 197.080, RSMo Supp. 2021. This rule previously filed as 19 CSR 30-20.021(3)(G). Original rule filed June 27, 2007, effective Feb. 29, 2008. Rescinded and readopted: Filed March 20, 2019, effective Nov. 30, 2019. Amended: Filed June 25, 2021, effective Dec. 30, 2021. *Original authority: 192.006, RSMo 1993, amended 1995; 197.080, RSMo 1953, amended 1993, 1995, 2013, 2017; and 338.165, RSMo 2014.*

Miscellaneous

190.255. Opioid overdose drugs and devices, first responder may administer, when — definition.

1. Any qualified first responder may obtain and administer naloxone, or any other drug or device approved by the United States Food and Drug Administration, that blocks the effects of an opioid overdose and is administered in a manner approved by the United States Food and Drug Administration to a person suffering from an apparent narcotic or opiate-related overdose in order to revive the person.

2. Any licensed drug distributor or pharmacy in Missouri may sell naloxone, or any other drug or device approved by the United States Food and Drug Administration, that blocks the effects of an opioid overdose and is administered in a manner approved by the United States Food and Drug Administration to qualified first responder agencies to allow the agency to stock naloxone or other such drugs or devices for the administration of such drug or device to persons suffering from an apparent narcotic or opiate overdose in order to revive the person.

3. For the purposes of this section, "qualified first responder" shall mean any fire department personnel, fire district personnel, or licensed emergency medical technician who is acting under the directives and established protocols of a medical director of a local licensed ground ambulance service licensed under section 190.109, or any state or local law enforcement agency staff member, who comes in contact with a person suffering from an apparent narcotic or opiate-related overdose and who has received training in recognizing and responding to a narcotic or opiate overdose and the administration of naloxone, or any other drug or device approved by the United States Food and Drug Administration, that blocks the effects of an opioid overdose and is administered in a manner approved by the United States Food and Drug Administration to a person suffering from an apparent narcotic or opiate-related overdose. "Qualified first responder agencies" shall mean any state or local law enforcement agency, fire department, or ambulance service that provides documented training to its staff related to the administration of naloxone or other such drugs or devices in an apparent narcotic or opiate overdose situation.

4. A qualified first responder shall only administer naloxone, or any other drug or device approved by the United States Food and Drug Administration, that blocks the effects of an opioid overdose and is administered in a manner approved by the United States Food and Drug Administration by such means as the qualified first responder has received training for the administration of naloxone or other such drugs or devices.

(L. 2014 H.B. 2040, A.L. 2023 S.B. 24 merged with S.B. 45 & 90 merged with S.B. 70 merged with S.B. 157 merged with S.B. 186)

196.095. When drug or device adulterated.

A drug or device shall be deemed to be adulterated:

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or

(2) If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or

(3) If it is a drug and its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(4) If it is a drug and it bears or contains, for purposes of coloring only, a coal tar color other than one from a batch certified under the authority of the federal act;

(5) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the federal act. No drug defined in an official compendium shall be deemed to be adulterated under this subdivision because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia;

(6) If it is not subject to the provisions of subdivision (5) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess;

(7) If it is a drug and any substance has been mixed or packed therewith so as to reduce its quality or strength, or substituted wholly or in part therefor.

(L. 1943 p. 559 § 9869)

196.100. When drug or device misbranded.

1. Any manufacturer, packer, distributor or seller of drugs or devices in this state shall comply with the current federal labeling requirements contained in the Federal Food, Drug and Cosmetic Act, as amended, and any federal regulations

promulgated thereunder. Any drug or device which contains labeling that is not in compliance with the provisions of this section shall be deemed misbranded.

2. A drug dispensed on an electronic prescription or a written prescription signed by a licensed physician, dentist, or veterinarian, except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to a diagnosis by mail, shall be exempt from the requirements of this section if such physician, dentist, or veterinarian is licensed by law to administer such drug, and such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian.

3. The department is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of sections 196.010 to 196.120, drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of said sections upon removal from such processing, labeling, or repacking establishment.

(L. 1943 p. 559 § 9870, A.L. 2001 H.B. 796 merged with S.B. 514, A.L. 2019 S.B. 514)

167.630. Epinephrine prefilled auto syringes, school nurse authorized to maintain adequate supply — administration authorized, when.

1. Each school board may authorize a school nurse licensed under chapter 335 who is employed by the school district and for whom the board is responsible for to maintain an adequate supply of prefilled auto syringes of epinephrine with fifteen-hundredths milligram or three-tenths milligram delivery at the school. The nurse shall recommend to the school board the number of prefilled epinephrine auto syringes that the school should maintain.

2. To obtain prefilled epinephrine auto syringes for a school district, a prescription written by a licensed physician, a physician's assistant, or nurse practitioner is required. For such prescriptions, the school district shall be designated as the patient, the nurse's name shall be required, and the prescription shall be filled at a licensed pharmacy.

3. A school nurse, contracted agent trained by a nurse, or other school employee trained by and supervised by the nurse shall have the discretion to use an epinephrine auto syringe on any student the school nurse, trained employee, or trained contracted agent believes is having a life-threatening anaphylactic reaction based on the training in recognizing an acute episode of an anaphylactic reaction. The provisions of section 167.624 concerning immunity from civil liability for trained employees administering lifesaving methods shall apply to trained employees administering a prefilled auto syringe under this section. Trained contracted agents shall have immunity from civil liability for administering a prefilled auto syringe under this section.

(L. 2006 H.B. 1245, A.L. 2010 H.B. 1543, A.L. 2022 S.B. 710)

167.635. Asthma-related rescue medications, school nurse may be authorized by school board to maintain, procedure.

1. Each school board may authorize a school nurse licensed under chapter 335 who is employed by the school district and for whom the board is responsible to maintain a supply of asthma-related rescue medications at the school. The nurse shall recommend to the school board the quantity of medication the school should maintain.

2. To obtain asthma rescue medications for a school district, a prescription written by a licensed physician, a physician's assistant, or nurse practitioner is required. For such prescriptions, the school district shall be designated as the patient, the nurse's name shall be required, and the prescription shall be filled at a licensed pharmacy.

3. A school nurse or other school employee trained by and supervised by the nurse shall have the discretion to use asthma-related rescue medications on any student the school nurse or trained employee believes is having a life-threatening asthma episode based on the training in recognizing an acute asthma episode. The provisions of section 167.624 concerning immunity from civil liability for trained employees administering lifesaving methods shall apply to trained employees administering an asthma-related rescue medication under this section.

(L. 2012 H.B. 1188)

196.990. Epinephrine auto-injectors, authorized entities may stock supply — definitions — procedure — immunity from liability — applicability.

1. As used in this section, the following terms shall mean:

(1) "Administer", the direct application of an epinephrine auto-injector to the body of an individual;

(2) "Authorized entity", any entity or organization at or in connection with which allergens capable of causing anaphylaxis may be present including, but not limited to, qualified first responders, as such term is defined in section 321.621, restaurants, recreation camps, youth sports leagues, amusement parks, and sports arenas. "Authorized entity" shall not include any public school or public charter school;

(3) "Epinephrine auto-injector", a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body;

(4) "Physician", a physician licensed in this state under chapter 334;

(5) "Provide", the supply of one or more epinephrine auto-injectors to an individual;

(6) "Self-administration", a person's discretionary use of an epinephrine auto-injector.

2. A physician may prescribe epinephrine auto-injectors in the name of an authorized entity for use in accordance with this section, and pharmacists, physicians, and other persons authorized to dispense prescription medications may dispense epinephrine auto-injectors under a prescription issued in the name of an authorized entity.

3. An authorized entity may acquire and stock a supply of epinephrine auto-injectors under a prescription issued in accordance with this section. Such epinephrine auto-injectors shall be stored in a location readily accessible in an emergency and in accordance with the epinephrine auto-injector's instructions for use and any additional requirements established by the department of health and senior services by rule. An authorized entity shall designate employees or agents who have completed the training required under this section to be responsible for the storage, maintenance, and general oversight of epinephrine auto-injectors acquired by the authorized entity.

4. An authorized entity that acquires a supply of epinephrine auto-injectors under a prescription issued in accordance with this section shall ensure that:

(1) Expected epinephrine auto-injector users receive training in recognizing symptoms of severe allergic reactions including anaphylaxis and the use of epinephrine auto-injectors from a nationally recognized organization experienced in training laypersons in emergency health treatment or another entity or person approved by the department of health and senior services;

(2) All epinephrine auto-injectors are maintained and stored according to the epinephrine auto-injector's instructions for use;

(3) Any person who provides or administers an epinephrine auto-injector to an individual who the person believes in good faith is experiencing anaphylaxis activates the emergency medical services system as soon as possible; and

(4) A proper review of all situations in which an epinephrine auto-injector is used to render emergency care is conducted.

5. Any authorized entity that acquires a supply of epinephrine auto-injectors under a prescription issued in accordance with this section shall notify the emergency communications district or the ambulance dispatch center of the primary provider of emergency medical services where the epinephrine auto-injectors are to be located within the entity's facility.

6. No person shall provide or administer an epinephrine auto-injector to any individual who is under eighteen years of age without the verbal consent of a parent or guardian who is present at the time when provision or administration of the epinephrine auto-injector is needed. Provided, however, that a person may provide or administer an epinephrine auto-injector to such an individual without the consent of a parent or guardian if the parent or guardian is not physically present and the person reasonably believes the individual shall be in imminent danger without the provision or administration of the epinephrine auto-injector.

7. The following persons and entities shall not be liable for any injuries or related damages that result from the administration or self-administration of an epinephrine auto-injector in accordance with this section that may constitute ordinary negligence:

(1) An authorized entity that possesses and makes available epinephrine auto-injectors and its employees, agents, and other trained persons;

(2) Any person who uses an epinephrine auto-injector made available under this section;

(3) A physician that prescribes epinephrine auto-injectors to an authorized entity; or

(4) Any person or entity that conducts the training described in this section.

Such immunity does not apply to acts or omissions constituting a reckless disregard for the safety of others or willful or wanton conduct. The administration of an epinephrine auto-injector in accordance with this section shall not be considered the practice of medicine. The immunity from liability provided under this subsection is in addition to and not in lieu of that provided under section 537.037. An authorized entity located in this state shall not be liable for any injuries or related damages that result from the provision or administration of an epinephrine auto-injector by its employees or agents outside of this state if the entity or its employee or agent is not liable for such injuries or related damages under the laws of the state in which such provision or administration occurred. No trained person who is in compliance with this section and who in good faith and exercising reasonable care fails to administer an epinephrine auto-injector shall be liable for such failure.

8. All basic life support ambulances and stretcher vans operated in the state shall be equipped with epinephrine auto-injectors and be staffed by at least one individual trained in the use of epinephrine auto-injectors.

9. The provisions of this section shall apply in all counties within the state and any city not within a county.

10. Nothing in this section shall be construed as superseding the provisions of section 167.630.

(L. 2017 S.B. 139 merged with S.B. 501, A.L. 2020 H.B. 1682)

321.621. Epinephrine auto-injector devices, statewide standing order issued for certain areas, when — limitation on possession and use — fund created.

1. For the purposes of this section, "qualified first responder" shall mean any state and local law enforcement agency staff, fire department personnel, fire district personnel, or licensed emergency medical technician who is acting under the directives and established protocols of a medical director who comes in contact with a person suffering from an anaphylactic reaction and who has received training in recognizing and responding to anaphylactic reactions and the administration of epinephrine auto-injector devices to a person suffering from an apparent anaphylactic reaction. "Qualified first responder agencies" shall mean any state or local law enforcement agency, fire department, or ambulance service that provides documented training

to its staff related to the administration of epinephrine auto-injector devices in an apparent anaphylactic reaction.

2. The director of the department of health and senior services, if a licensed physician, may issue a statewide standing order for epinephrine auto-injector devices for adult patients to fire protection districts in nonmetropolitan areas in Missouri as such areas are determined according to the United States Census Bureau's American Community Survey, based on the most recent of five-year period estimate data in which the final year of the estimate ends in either zero or five. If the director of the department of health and senior services is not a licensed physician, the department of health and senior services may employ or contract with a licensed physician who may issue such a statewide order with the express consent of the director.

3. Possession and use of epinephrine auto-injector devices for adult patients shall be limited as follows:

(1) No person shall use an epinephrine auto-injector device pursuant to this section unless such person has successfully completed a training course in the use of epinephrine auto-injector devices for adult patients approved by the director of the department of health and senior services. Nothing in this section shall prohibit the use of an epinephrine auto-injector device:

(a) By a health care professional licensed or certified by this state who is acting within the scope of his or her practice; or

(b) By a person acting pursuant to a lawful prescription;

(2) Every person, firm, organization and entity authorized to possess and use epinephrine auto-injector devices for adult patients pursuant to this section shall use, maintain and dispose of such devices for adult patients in accordance with the rules of the department;

(3) Every use of an epinephrine auto-injector device pursuant to this section shall immediately be reported to the emergency health care provider as defined in section 190.246.

4. (1) Use of an epinephrine auto-injector device pursuant to this section shall be considered first aid or emergency treatment for the purpose of any law relating to liability.

(2) Purchase, acquisition, possession or use of an epinephrine auto-injector device pursuant to this section shall not constitute the unlawful practice of medicine or the unlawful practice of a profession.

(3) Any person otherwise authorized to sell or provide an epinephrine auto-injector device may sell or provide it to a person authorized to possess it pursuant to this section.

5. (1) There is hereby created in the state treasury the "Epinephrine Auto-injector Devices for Fire Personnel Fund", which shall consist of money collected under this section. The state treasurer shall be custodian of the fund. In accordance with sections 30.170 and 30.180, the state treasurer may approve disbursements. The moneys in the fund as set forth in this section shall be subject to appropriation by the general assembly for the particular purpose for which collected. The fund shall be a dedicated fund and money in the fund shall be used solely by the department of health and senior services for the purposes of providing epinephrine auto-injector devices for adult patients to qualified first responder agencies as used in this section.

(2) Notwithstanding the provisions of section 33.080 to the contrary, any moneys remaining in the fund at the end of the biennium shall not revert to the credit of the general revenue fund.

(3) The state treasurer shall invest moneys in the fund in the same manner as other funds are invested. Any interest and moneys earned on such investments shall be credited to the fund.

(L. 2020 H.B. 1682)

383.133. Reports by hospitals, ambulatory surgical centers, nursing homes, and licensing authorities, when, contents, limited use, penalty.

1. The chief executive office or similarly empowered official of any hospital, ambulatory surgical center, as such terms are defined in chapter 197, temporary nursing staffing agency, nursing home, any nursing facility as such term is defined in chapter 198, or any entity that employs or contracts with licensed health care professionals to provide health care services to individuals shall report to the appropriate health care professional licensing authority any disciplinary action against any health care professional or the voluntary resignation of any health care professional against whom any complaints or reports have been made which might have led to disciplinary action.

2. All reports required by this section shall be submitted within fifteen days of the final disciplinary action and shall contain, but need not be limited to, the following information:

(1) The name, address and telephone number of the person making the report;

(2) The name, address and telephone number of the person who is the subject of the report;

(3) A description of the facts, including as much detail and information as possible, which gave rise to the issuance of the report, including the dates of occurrence deemed to necessitate the filing of the report;

(4) If court action is involved and known to the reporting agent, the identity of the court, including the date of filing and the docket number of the action.

3. Upon request, the licensing authority may furnish a report of any disciplinary action received by it under the provisions of this section to any entity required to report under this section. Such licensing authority may also furnish, upon request, a report of disciplinary action taken by the licensing authority to any other administrative or law enforcement agency acting within the scope of its statutory authority.

4. There shall be no liability on the part of, and no cause of action of any nature shall arise against any health care

professional licensing authority or any entity required to report under this section, or any of their agents or employees for any action taken in good faith and without malice in carrying out the provisions of this section.

5. Neither a report required to be filed under subsection 2 of this section nor the record of any proceeding shall be used against a health care professional in any other administrative or judicial proceeding.

6. Violation of any provision of this section is an infraction.

(L. 1986 S.B. 663 § 2, A.L. 2007 H.B. 780 merged with S.B. 308, A.L. 2010 H.B. 2226, et al.)

(2001) Statements made in incident report by hospital to state board of nursing about nurse were not, in absence of actual proceedings pending against that nurse, entitled to absolute immunity from nurse's libel claim. Haynes-Wilkinson v. Barnes-Jewish Hospital, 131 F.Supp.2d 1140 (E.D.Mo.).

Mid-Level Practitioner Collaborative Practice

334.037. Assistant physicians, collaborative practice arrangements, requirements — rulemaking authority — identification badges required, when — prescriptive authority.

1. A physician may enter into collaborative practice arrangements with assistant physicians. Collaborative practice arrangements shall be in the form of written agreements, jointly agreed-upon protocols, or standing orders for the delivery of health care services. Collaborative practice arrangements, which shall be in writing, may delegate to an assistant physician the authority to administer or dispense drugs and provide treatment as long as the delivery of such health care services is within the scope of practice of the assistant physician and is consistent with that assistant physician's skill, training, and competence and the skill and training of the collaborating physician.

2. The written collaborative practice arrangement shall contain at least the following provisions:

(1) Complete names, home and business addresses, zip codes, and telephone numbers of the collaborating physician and the assistant physician;

(2) A list of all other offices or locations besides those listed in subdivision (1) of this subsection where the collaborating physician authorized the assistant physician to prescribe;

(3) A requirement that there shall be posted at every office where the assistant physician is authorized to prescribe, in collaboration with a physician, a prominently displayed disclosure statement informing patients that they may be seen by an assistant physician and have the right to see the collaborating physician;

(4) All specialty or board certifications of the collaborating physician and all certifications of the assistant physician;

(5) The manner of collaboration between the collaborating physician and the assistant physician, including how the collaborating physician and the assistant physician shall:

(a) Engage in collaborative practice consistent with each professional's skill, training, education, and competence;

(b) Maintain geographic proximity; except, the collaborative practice arrangement may allow for geographic proximity to be waived for a maximum of twenty-eight days per calendar year for rural health clinics as defined by Pub. L. 95-210 (42 U.S.C. Section 1395x), as amended, as long as the collaborative practice arrangement includes alternative plans as required in paragraph (c) of this subdivision. Such exception to geographic proximity shall apply only to independent rural health clinics, provider-based rural health clinics if the provider is a critical access hospital as provided in 42 U.S.C. Section 1395i-4, and provider-based rural health clinics if the main location of the hospital sponsor is greater than fifty miles from the clinic. The collaborating physician shall maintain documentation related to such requirement and present it to the state board of registration for the healing arts when requested; and

(c) Provide coverage during absence, incapacity, infirmity, or emergency by the collaborating physician;

(6) A description of the assistant physician's controlled substance prescriptive authority in collaboration with the physician, including a list of the controlled substances the physician authorizes the assistant physician to prescribe and documentation that it is consistent with each professional's education, knowledge, skill, and competence;

(7) A list of all other written practice agreements of the collaborating physician and the assistant physician;

(8) The duration of the written practice agreement between the collaborating physician and the assistant physician;

(9) A description of the time and manner of the collaborating physician's review of the assistant physician's delivery of health care services. The description shall include provisions that the assistant physician shall submit a minimum of ten percent of the charts documenting the assistant physician's delivery of health care services to the collaborating physician for review by the collaborating physician, or any other physician designated in the collaborative practice arrangement, every fourteen days; and

(10) The collaborating physician, or any other physician designated in the collaborative practice arrangement, shall review every fourteen days a minimum of twenty percent of the charts in which the assistant physician prescribes controlled substances. The charts reviewed under this subdivision may be counted in the number of charts required to be reviewed under subdivision (9) of this subsection.

3. The state board of registration for the healing arts under section 334.125 shall promulgate rules regulating the use of collaborative practice arrangements for assistant physicians. Such rules shall specify:

(1) Geographic areas to be covered;

(2) The methods of treatment that may be covered by collaborative practice arrangements;

(3) In conjunction with deans of medical schools and primary care residency program directors in the state, the development and implementation of educational methods and programs undertaken during the collaborative practice service which shall facilitate the advancement of the assistant physician's medical knowledge and capabilities, and which may lead to credit toward a future residency program for programs that deem such documented educational achievements acceptable; and

(4) The requirements for review of services provided under collaborative practice arrangements, including delegating authority to prescribe controlled substances.

Any rules relating to dispensing or distribution of medications or devices by prescription or prescription drug orders under this section shall be subject to the approval of the state board of pharmacy. Any rules relating to dispensing or distribution of controlled substances by prescription or prescription drug orders under this section shall be subject to the approval of the department of health and senior services and the state board of pharmacy. The state board of registration for the healing arts shall promulgate rules applicable to assistant physicians that shall be consistent with guidelines for federally funded clinics. The rulemaking authority granted in this subsection shall not extend to collaborative practice arrangements

of hospital employees providing inpatient care within hospitals as defined in chapter 197 or population-based public health services as defined by 20 CSR 2150-5.100 as of April 30, 2008.

4. The state board of registration for the healing arts shall not deny, revoke, suspend, or otherwise take disciplinary action against a collaborating physician for health care services delegated to an assistant physician provided the provisions of this section and the rules promulgated thereunder are satisfied.

5. Within thirty days of any change and on each renewal, the state board of registration for the healing arts shall require every physician to identify whether the physician is engaged in any collaborative practice arrangement, including collaborative practice arrangements delegating the authority to prescribe controlled substances, and also report to the board the name of each assistant physician with whom the physician has entered into such arrangement. The board may make such information available to the public. The board shall track the reported information and may routinely conduct random reviews of such arrangements to ensure that arrangements are carried out for compliance under this chapter.

6. A collaborating physician shall not enter into a collaborative practice arrangement with more than six full-time equivalent assistant physicians, full-time equivalent physician assistants, or full-time equivalent advance practice registered nurses, or any combination thereof. Such limitation shall not apply to collaborative arrangements of hospital employees providing inpatient care service in hospitals as defined in chapter 197 or population-based public health services as defined by 20 CSR 2150-5.100 as of April 30, 2008, or to a certified registered nurse anesthetist providing anesthesia services under the supervision of an anesthesiologist or other physician, dentist, or podiatrist who is immediately available if needed as set out in subsection 7 of section 334.104.

7. The collaborating physician shall determine and document the completion of at least a one-month period of time during which the assistant physician shall practice with the collaborating physician continuously present before practicing in a setting where the collaborating physician is not continuously present. No rule or regulation shall require the collaborating physician to review more than ten percent of the assistant physician's patient charts or records during such one-month period. Such limitation shall not apply to collaborative arrangements of providers of population-based public health services as defined by 20 CSR 2150-5.100 as of April 30, 2008.

8. No agreement made under this section shall supersede current hospital licensing regulations governing hospital medication orders under protocols or standing orders for the purpose of delivering inpatient or emergency care within a hospital as defined in section 197.020 if such protocols or standing orders have been approved by the hospital's medical staff and pharmaceutical therapeutics committee.

9. No contract or other agreement shall require a physician to act as a collaborating physician for an assistant physician against the physician's will. A physician shall have the right to refuse to act as a collaborating physician, without penalty, for a particular assistant physician. No contract or other agreement shall limit the collaborating physician's ultimate authority over any protocols or standing orders or in the delegation of the physician's authority to any assistant physician, but such requirement shall not authorize a physician in implementing such protocols, standing orders, or delegation to violate applicable standards for safe medical practice established by a hospital's medical staff.

10. No contract or other agreement shall require any assistant physician to serve as a collaborating assistant physician for any collaborating physician against the assistant physician's will. An assistant physician shall have the right to refuse to collaborate, without penalty, with a particular physician.

11. All collaborating physicians and assistant physicians in collaborative practice arrangements shall wear identification badges while acting within the scope of their collaborative practice arrangement. The identification badges shall prominently display the licensure status of such collaborating physicians and assistant physicians.

12. (1) An assistant physician with a certificate of controlled substance prescriptive authority as provided in this section may prescribe any controlled substance listed in Schedule III, IV, or V of section 195.017, and may have restricted authority in Schedule II, when delegated the authority to prescribe controlled substances in a collaborative practice arrangement. Prescriptions for Schedule II medications prescribed by an assistant physician who has a certificate of controlled substance prescriptive authority are restricted to only those medications containing hydrocodone. Such authority shall be filed with the state board of registration for the healing arts. The collaborating physician shall maintain the right to limit a specific scheduled drug or scheduled drug category that the assistant physician is permitted to prescribe. Any limitations shall be listed in the collaborative practice arrangement. Assistant physicians shall not prescribe controlled substances for themselves or members of their families. Schedule III controlled substances and Schedule II - hydrocodone prescriptions shall be limited to a five-day supply without refill, except that buprenorphine may be prescribed for up to a thirty-day supply without refill for patients receiving medication-assisted treatment for substance use disorders under the direction of the collaborating physician. Assistant physicians who are authorized to prescribe controlled substances under this section shall register with the federal Drug Enforcement Administration and the state bureau of narcotics and dangerous drugs, and shall include the Drug Enforcement Administration registration number on prescriptions for controlled substances.

(2) The collaborating physician shall be responsible to determine and document the completion of at least one hundred twenty hours in a four-month period by the assistant physician during which the assistant physician shall practice with the collaborating physician on-site prior to prescribing controlled substances when the collaborating physician is not on-site. Such limitation shall not apply to assistant physicians of population-based public health services as defined in 20 CSR 2150-5.100 as of April 30, 2009, or assistant physicians providing opioid addiction treatment.

(3) An assistant physician shall receive a certificate of controlled substance prescriptive authority from the state board

of registration for the healing arts upon verification of licensure under section 334.036.

13. Nothing in this section or section 334.036 shall be construed to limit the authority of hospitals or hospital medical staff to make employment or medical staff credentialing or privileging decisions.

(L. 2014 S.B. 716 merged with S.B. 754, A.L. 2015 H.B. 709, A.L. 2018 S.B. 718 merged with S.B. 951, A.L. 2019 S.B. 514)

334.104. Collaborative practice arrangements, form, contents, delegation of authority — rules, approval, restrictions — disciplinary actions — notice of collaborative practice or physician assistant agreements to board, when — certain nurses may provide anesthesia services, when — contract limitations.

1. A physician may enter into collaborative practice arrangements with registered professional nurses. Collaborative practice arrangements shall be in the form of written agreements, jointly agreed-upon protocols, or standing orders for the delivery of health care services. Collaborative practice arrangements, which shall be in writing, may delegate to a registered professional nurse the authority to administer or dispense drugs and provide treatment as long as the delivery of such health care services is within the scope of practice of the registered professional nurse and is consistent with that nurse's skill, training and competence.

2. (1) Collaborative practice arrangements, which shall be in writing, may delegate to a registered professional nurse the authority to administer, dispense or prescribe drugs and provide treatment if the registered professional nurse is an advanced practice registered nurse as defined in subdivision (2) of section 335.016. Collaborative practice arrangements may delegate to an advanced practice registered nurse, as defined in section 335.016, the authority to administer, dispense, or prescribe controlled substances listed in Schedules III, IV, and V of section 195.017, and Schedule II - hydrocodone; except that, the collaborative practice arrangement shall not delegate the authority to administer any controlled substances listed in Schedules III, IV, and V of section 195.017, or Schedule II - hydrocodone for the purpose of inducing sedation or general anesthesia for therapeutic, diagnostic, or surgical procedures. Schedule III narcotic controlled substance and Schedule II - hydrocodone prescriptions shall be limited to a one hundred twenty-hour supply without refill.

(2) Notwithstanding any other provision of this section to the contrary, a collaborative practice arrangement may delegate to an advanced practice registered nurse the authority to administer, dispense, or prescribe Schedule II controlled substances for hospice patients; provided, that the advanced practice registered nurse is employed by a hospice provider certified pursuant to chapter 197 and the advanced practice registered nurse is providing care to hospice patients pursuant to a collaborative practice arrangement that designates the certified hospice as a location where the advanced practice registered nurse is authorized to practice and prescribe.

(3) Such collaborative practice arrangements shall be in the form of written agreements, jointly agreed-upon protocols or standing orders for the delivery of health care services.

(4) An advanced practice registered nurse may prescribe buprenorphine for up to a thirty-day supply without refill for patients receiving medication-assisted treatment for substance use disorders under the direction of the collaborating physician.

3. The written collaborative practice arrangement shall contain at least the following provisions:

(1) Complete names, home and business addresses, zip codes, and telephone numbers of the collaborating physician and the advanced practice registered nurse;

(2) A list of all other offices or locations besides those listed in subdivision (1) of this subsection where the collaborating physician authorized the advanced practice registered nurse to prescribe;

(3) A requirement that there shall be posted at every office where the advanced practice registered nurse is authorized to prescribe, in collaboration with a physician, a prominently displayed disclosure statement informing patients that they may be seen by an advanced practice registered nurse and have the right to see the collaborating physician;

(4) All specialty or board certifications of the collaborating physician and all certifications of the advanced practice registered nurse;

(5) The manner of collaboration between the collaborating physician and the advanced practice registered nurse, including how the collaborating physician and the advanced practice registered nurse will:

(a) Engage in collaborative practice consistent with each professional's skill, training, education, and competence;

(b) Maintain geographic proximity, except as specified in this paragraph. The following provisions shall apply with respect to this requirement:

a. Until August 28, 2025, an advanced practice registered nurse providing services in a correctional center, as defined in section 217.010, and his or her collaborating physician shall satisfy the geographic proximity requirement if they practice within two hundred miles by road of one another. An incarcerated patient who requests or requires a physician consultation shall be treated by a physician as soon as appropriate;

b. The collaborative practice arrangement may allow for geographic proximity to be waived for a maximum of twenty-eight days per calendar year for rural health clinics as defined by Pub.L. 95-210 (42 U.S.C. Section 1395x, as amended), as long as the collaborative practice arrangement includes alternative plans as required in paragraph (c) of this subdivision. This exception to geographic proximity shall apply only to independent rural health clinics, provider-based rural health clinics where the provider is a critical access hospital as provided in 42 U.S.C. Section 1395i-4, and provider-based rural health clinics where the main location of the hospital sponsor is greater than

fifty miles from the clinic;

c. The collaborative practice arrangement may allow for geographic proximity to be waived when the arrangement outlines the use of telehealth, as defined in section 191.1145;

d. In addition to the waivers and exemptions provided in this subsection, an application for a waiver for any other reason of any applicable geographic proximity shall be available if a physician is collaborating with an advanced practice registered nurse in excess of any geographic proximity limit. The board of nursing and the state board of registration for the healing arts shall review each application for a waiver of geographic proximity and approve the application if the boards determine that adequate supervision exists between the collaborating physician and the advanced practice registered nurse. The boards shall have forty-five calendar days to review the completed application for the waiver of geographic proximity. If no action is taken by the boards within forty-five days after the submission of the application for a waiver, then the application shall be deemed approved. If the application is denied by the boards, the provisions of section 536.063 for contested cases shall apply and govern proceedings for appellate purposes; and

e. The collaborating physician is required to maintain documentation related to this requirement and to present it to the state board of registration for the healing arts when requested; and

(c) Provide coverage during absence, incapacity, infirmity, or emergency by the collaborating physician;

(6) A description of the advanced practice registered nurse's controlled substance prescriptive authority in collaboration with the physician, including a list of the controlled substances the physician authorizes the nurse to prescribe and documentation that it is consistent with each professional's education, knowledge, skill, and competence;

(7) A list of all other written practice agreements of the collaborating physician and the advanced practice registered nurse;

(8) The duration of the written practice agreement between the collaborating physician and the advanced practice registered nurse;

(9) A description of the time and manner of the collaborating physician's review of the advanced practice registered nurse's delivery of health care services. The description shall include provisions that the advanced practice registered nurse shall submit a minimum of ten percent of the charts documenting the advanced practice registered nurse's delivery of health care services to the collaborating physician for review by the collaborating physician, or any other physician designated in the collaborative practice arrangement, every fourteen days;

(10) The collaborating physician, or any other physician designated in the collaborative practice arrangement, shall review every fourteen days a minimum of twenty percent of the charts in which the advanced practice registered nurse prescribes controlled substances. The charts reviewed under this subdivision may be counted in the number of charts required to be reviewed under subdivision (9) of this subsection; and

(11) If a collaborative practice arrangement is used in clinical situations where a collaborating advanced practice registered nurse provides health care services that include the diagnosis and initiation of treatment for acutely or chronically ill or injured persons, then the collaborating physician or any other physician designated in the collaborative practice arrangement shall be present for sufficient periods of time, at least once every two weeks, except in extraordinary circumstances that shall be documented, to participate in a chart review and to provide necessary medical direction, medical services, consultations, and supervision of the health care staff.

4. The state board of registration for the healing arts pursuant to section 334.125 and the board of nursing pursuant to section 335.036 may jointly promulgate rules regulating the use of collaborative practice arrangements. Such rules shall be limited to the methods of treatment that may be covered by collaborative practice arrangements and the requirements for review of services provided pursuant to collaborative practice arrangements including delegating authority to prescribe controlled substances. Any rules relating to geographic proximity shall allow a collaborating physician and a collaborating advanced practice registered nurse to practice within two hundred miles by road of one another until August 28, 2025, if the nurse is providing services in a correctional center, as defined in section 217.010. Any rules relating to dispensing or distribution of medications or devices by prescription or prescription drug orders under this section shall be subject to the approval of the state board of pharmacy. Any rules relating to dispensing or distribution of controlled substances by prescription or prescription drug orders under this section shall be subject to the approval of the department of health and senior services and the state board of pharmacy. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither the state board of registration for the healing arts nor the board of nursing may separately promulgate rules relating to collaborative practice arrangements. Such jointly promulgated rules shall be consistent with guidelines for federally funded clinics. The rulemaking authority granted in this subsection shall not extend to collaborative practice arrangements of hospital employees providing inpatient care within hospitals as defined pursuant to chapter 197 or population-based public health services as defined by 20 CSR 2150- 5.100 as of April 30, 2008.

5. The state board of registration for the healing arts shall not deny, revoke, suspend or otherwise take disciplinary action against a physician for health care services delegated to a registered professional nurse provided the provisions of this section and the rules promulgated thereunder are satisfied. Upon the written request of a physician subject to a disciplinary action imposed as a result of an agreement between a physician and a registered professional nurse or registered physician assistant, whether written or not, prior to August 28, 1993, all records of such disciplinary licensure action and all records pertaining to the filing, investigation or review of an alleged violation of this chapter incurred as a result of such an agreement shall be removed from the records of the state board of registration for the healing arts and the division of professional

registration and shall not be disclosed to any public or private entity seeking such information from the board or the division. The state board of registration for the healing arts shall take action to correct reports of alleged violations and disciplinary actions as described in this section which have been submitted to the National Practitioner Data Bank. In subsequent applications or representations relating to his or her medical practice, a physician completing forms or documents shall not be required to report any actions of the state board of registration for the healing arts for which the records are subject to removal under this section.

6. Within thirty days of any change and on each renewal, the state board of registration for the healing arts shall require every physician to identify whether the physician is engaged in any collaborative practice arrangement, including collaborative practice arrangements delegating the authority to prescribe controlled substances, or physician assistant collaborative practice arrangement and also report to the board the name of each licensed professional with whom the physician has entered into such arrangement. The board shall make this information available to the public. The board shall track the reported information and may routinely conduct random reviews of such arrangements to ensure that arrangements are carried out for compliance under this chapter.

7. Notwithstanding any law to the contrary, a certified registered nurse anesthetist as defined in subdivision (8) of section 335.016 shall be permitted to provide anesthesia services without a collaborative practice arrangement provided that he or she is under the supervision of an anesthesiologist or other physician, dentist, or podiatrist who is immediately available if needed. Nothing in this subsection shall be construed to prohibit or prevent a certified registered nurse anesthetist as defined in subdivision (8) of section 335.016 from entering into a collaborative practice arrangement under this section, except that the collaborative practice arrangement may not delegate the authority to prescribe any controlled substances listed in Schedules III, IV, and V of section 195.017, or Schedule II - hydrocodone.

8. A collaborating physician shall not enter into a collaborative practice arrangement with more than six full-time equivalent advanced practice registered nurses, full-time equivalent licensed physician assistants, or full-time equivalent assistant physicians, or any combination thereof. This limitation shall not apply to collaborative arrangements of hospital employees providing inpatient care service in hospitals as defined in chapter 197 or population-based public health services as defined by 20 CSR 2150- 5.100 as of April 30, 2008, or to a certified registered nurse anesthetist providing anesthesia services under the supervision of an anesthesiologist or other physician, dentist, or podiatrist who is immediately available if needed as set out in subsection 7 of this section.

9. It is the responsibility of the collaborating physician to determine and document the completion of at least a one-month period of time during which the advanced practice registered nurse shall practice with the collaborating physician continuously present before practicing in a setting where the collaborating physician is not continuously present. This limitation shall not apply to collaborative arrangements of providers of population-based public health services, as defined by 20 CSR 2150- 5.100 as of April 30, 2008, or to collaborative practice arrangements between a primary care physician and a primary care advanced practice registered nurse or a behavioral health physician and a behavioral health advanced practice registered nurse, where the collaborating physician is new to a patient population to which the advanced practice registered nurse is familiar.

10. No agreement made under this section shall supersede current hospital licensing regulations governing hospital medication orders under protocols or standing orders for the purpose of delivering inpatient or emergency care within a hospital as defined in section 197.020 if such protocols or standing orders have been approved by the hospital's medical staff and pharmaceutical therapeutics committee.

11. No contract or other term of employment shall require a physician to act as a collaborating physician for an advanced practice registered nurse against the physician's will. A physician shall have the right to refuse to act as a collaborating physician, without penalty, for a particular advanced practice registered nurse. No contract or other agreement shall limit the collaborating physician's ultimate authority over any protocols or standing orders or in the delegation of the physician's authority to any advanced practice registered nurse, but this requirement shall not authorize a physician in implementing such protocols, standing orders, or delegation to violate applicable standards for safe medical practice established by hospital's medical staff.

12. No contract or other term of employment shall require any advanced practice registered nurse to serve as a collaborating advanced practice registered nurse for any collaborating physician against the advanced practice registered nurse's will. An advanced practice registered nurse shall have the right to refuse to collaborate, without penalty, with a particular physician.

(L. 1993 H.B. 564, A.L. 2002 S.B. 1182, A.L. 2003 H.B. 390, A.L. 2006 H.B. 1515 merged with S.B. 756, A.L. 2008 S.B. 724, A.L. 2009 H.B. 247, A.L. 2012 H.B. 1563, A.L. 2013 S.B. 330, A.L. 2015 H.B. 709, A.L. 2018 S.B. 718 merged with S.B. 951, A.L. 2019 S.B. 514, A.L. 2023 H.B. 115 & 99 merged with H.B. 402 merged with S.B. 45 & 90 merged with S.B. 70 merged with S.B. 157)

334.747. Prescribing controlled substances authorized, when — collaborating physicians — certification.

1. (1) A physician assistant with a certificate of controlled substance prescriptive authority as provided in this section may prescribe any controlled substance listed in Schedule III, IV, or V of section 195.017, and may have restricted authority in Schedule II, when delegated the authority to prescribe controlled substances in a collaborative practice arrangement. Such authority shall be listed on the collaborating physician form on file with the state board of healing arts. The collaborating

physician shall maintain the right to limit a specific scheduled drug or scheduled drug category that the physician assistant is permitted to prescribe. Any limitations shall be listed on the collaborating physician form. Prescriptions for Schedule II medications prescribed by a physician assistant with authority to prescribe delegated in a collaborative practice arrangement are restricted to only those medications containing hydrocodone. Physician assistants shall not prescribe controlled substances for themselves or members of their families. Schedule III narcotic controlled substances and Schedule II - hydrocodone prescriptions shall be limited to a five-day supply without refill, except that buprenorphine may be prescribed for up to a thirty-day supply without refill for patients receiving medication-assisted treatment for substance use disorders under the direction of the collaborating physician. Physician assistants who are authorized to prescribe controlled substances under this section shall register with the federal Drug Enforcement Administration and the state bureau of narcotics and dangerous drugs, and shall include the Drug Enforcement Administration registration number on prescriptions for controlled substances.

(2) Notwithstanding any other provision of this section to the contrary, a collaborative practice arrangement may delegate to a physician assistant the authority to administer, dispense, or prescribe Schedule II controlled substances for hospice patients; provided, that the physician assistant is employed by a hospice provider certified pursuant to chapter 197 and the physician assistant is providing care to hospice patients pursuant to a collaborative practice arrangement that designates the certified hospice as a location where the physician assistant is authorized to practice and prescribe.

2. The collaborating physician shall be responsible to determine and document the completion of at least one hundred twenty hours in a four-month period by the physician assistant during which the physician assistant shall practice with the collaborating physician on-site prior to prescribing controlled substances when the collaborating physician is not on-site. Such limitation shall not apply to physician assistants of population-based public health services as defined in 20 CSR 2150-5.100 as of April 30, 2009.

3. A physician assistant shall receive a certificate of controlled substance prescriptive authority from the board of healing arts upon verification of the completion of the following educational requirements:

(1) Successful completion of an advanced pharmacology course that includes clinical training in the prescription of drugs, medicines, and therapeutic devices. A course or courses with advanced pharmacological content in a physician assistant program accredited by the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA) or its predecessor agency shall satisfy such requirement;

(2) Completion of a minimum of three hundred clock hours of clinical training by the collaborating physician in the prescription of drugs, medicines, and therapeutic devices;

(3) Completion of a minimum of one year of supervised clinical practice or supervised clinical rotations. One year of clinical rotations in a program accredited by the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA) or its predecessor agency, which includes pharmacotherapeutics as a component of its clinical training, shall satisfy such requirement. Proof of such training shall serve to document experience in the prescribing of drugs, medicines, and therapeutic devices;

(4) A physician assistant previously licensed in a jurisdiction where physician assistants are authorized to prescribe controlled substances may obtain a state bureau of narcotics and dangerous drugs registration if a collaborating physician can attest that the physician assistant has met the requirements of subdivisions (1) to (3) of this subsection and provides documentation of existing federal Drug Enforcement Agency registration.

(L. 2009 S.B. 296, A.L. 2012 H.B. 1563, A.L. 2015 H.B. 709, A.L. 2018 S.B. 718 merged with S.B. 951, A.L. 2019 S.B. 514, A.L. 2023 H.B. 402 merged with S.B. 70 merged with S.B. 157)

Controlled Substance Criminal Offenses (Excerpts)

CONTROLLED SUBSTANCE CRIMINAL OFFENSES (EXCERPTS)

579.015. Possession or control of a controlled substance — penalty.

1. A person commits the offense of possession of a controlled substance if he or she knowingly possesses a controlled substance, except as authorized by this chapter or chapter 195.

2. The offense of possession of any controlled substance except thirty-five grams or less of marijuana or any synthetic cannabinoid is a class D felony.

3. The offense of possession of more than ten grams but thirty-five grams or less of marijuana or any synthetic cannabinoid is a class A misdemeanor.

4. The offense of possession of not more than ten grams of marijuana or any synthetic cannabinoid is a class D misdemeanor. If the defendant has previously been found guilty of any offense of the laws related to controlled substances of this state, or of the United States, or any state, territory, or district, the offense is a class A misdemeanor. Prior findings of guilt shall be pleaded and proven in the same manner as required by section 558.021.

5. In any complaint, information, or indictment, and in any action or proceeding brought for the enforcement of any provision of this chapter or chapter 195, it shall not be necessary to include any exception, excuse, proviso, or exemption contained in this chapter or chapter 195, and the burden of proof of any such exception, excuse, proviso or exemption shall be upon the defendant.

(L. 1989 S.B. 215 & 58, A.L. 2010 H.B. 1472, A.L. 2011 H.B. 641, A.L. 2014 S.B. 491, A.L. 2016 H.B. 2332)
Transferred 2014; formerly 195.202; Effective 1-01-17

579.020. Delivery of a controlled substance — penalties.

1. A person commits the offense of delivery of a controlled substance if, except as authorized in this chapter or chapter 195, he or she:
   (1) Knowingly distributes or delivers a controlled substance;
   (2) Attempts to distribute or deliver a controlled substance;
   (3) Knowingly possesses a controlled substance with the intent to distribute or deliver any amount of a controlled substance; or
   (4) Knowingly permits a minor to purchase or transport illegally obtained controlled substances.

2. Except when the controlled substance is thirty-five grams or less of marijuana or synthetic cannabinoid or as otherwise provided under subsection 5 of this section, the offense of delivery of a controlled substance is a class C felony.

3. Except as otherwise provided under subsection 4 of this section, the offense of delivery of thirty-five grams or less of marijuana or synthetic cannabinoid is a class E felony.

4. The offense of delivery of thirty-five grams or less of marijuana or synthetic cannabinoid to a person less than seventeen years of age who is at least two years younger than the defendant is a class C felony.

5. The offense of delivery of a controlled substance is a class B felony if:
   (1) The delivery or distribution is any amount of a controlled substance except thirty-five grams or less of marijuana or synthetic cannabinoid, to a person less than seventeen years of age who is at least two years younger than the defendant; or
   (2) The person knowingly permits a minor to purchase or transport illegally obtained controlled substances.

(L. 1989 S.B. 215 & 58, A.L. 2014 S.B. 491)
Transferred 2014; formerly 195.212; Effective 1-01-17

579.030. Distribution of controlled substance in a protected location — penalty.

1. A person commits the offense of distribution of a controlled substance in a protected location if he or she knowingly distributes, sells, or delivers any controlled substance, except thirty-five grams or less of marijuana or synthetic cannabinoid, to a person with knowledge that that distribution, delivery or sale is:
   (1) In, on, or within two thousand feet of, the real property comprising a public or private elementary, vocational, or secondary school, or on any school bus; or
   (2) In, on, or within one thousand feet of, the real property comprising a public park, state park, county park, municipal park, or private park designed for public recreational purposes, as park is defined in section 253.010; or
   (3) In or on the real property comprising public housing or other governmental assisted housing.

2. The offense of unlawful distribution of a controlled substance in a protected location is a class A felony.

(L. 1993 S.B. 180, A.L. 2003 S.B. 39, A.L. 2014 S.B. 491)
Transferred 2014; formerly 195.218; Effective 1-01-17

579.040. Unlawful distribution, delivery, or sale of drug paraphernalia — penalties.

1. A person commits the offense of unlawful distribution, delivery, or sale of drug paraphernalia if he or she unlawfully

distributes, delivers, or sells, or possesses with intent to distribute, deliver, or sell drug paraphernalia knowing, or under circumstances in which one reasonably should know, that it will be used to plant, propogate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance or an imitation controlled substance in violation of this chapter.

2. The offense of unlawful delivery of drug paraphernalia is a class A misdemeanor, unless done for commercial purposes, in which case it is a class E felony.

(L. 2014 S.B. 491)
Effective 1-01-17

579.045. Fraudulently attempting to obtain a controlled substance — penalty.

1. A person commits the offense of fraudulently attempting to obtain a controlled substance if he or she knowingly obtains or attempts to obtain a controlled substance, or knowingly procures or attempts to procure an administration of the controlled substance by fraud. The offense of fraudulently attempting to obtain a controlled substance shall include, but shall not be limited to nor be limited by, the following:

(1) Knowingly making a false statement in any prescription, order, report, or record, required by this chapter or chapter 195;

(2) For the purpose of obtaining a controlled substance, falsely assuming the title of, or representing oneself to be, a manufacturer, wholesaler, pharmacist, physician, dentist, podiatrist, veterinarian, nurse, or other authorized person;

(3) Making or uttering any false or forged prescription or false or forged written order;

(4) Affixing any false or forged label to a package or receptacle containing controlled substances;

(5) Possess a false or forged prescription with intent to obtain a controlled substance.

2. The offense of fraudulently attempting to obtain a controlled substance is a class E felony.

3. Information communicated to a physician in an effort unlawfully to procure a controlled substance or unlawfully to procure the administration of any such drug is not deemed a privileged communication; provided, however, that no physician or surgeon shall be competent to testify concerning any information which he or she may have acquired from any patient while attending him or her in a professional character and which information was necessary to enable him or her to prescribe for such patient as a physician, or to perform any act for him or her as a surgeon.

(L. 1989 S.B. 215 & 58, A.L. 1997 H.B. 635, A.L. 2014 S.B. 491)
Transferred 2014; formerly 195.204; Effective 1-01-17

579.050. Manufacture of an imitation controlled substance — penalty.

1. A person commits the offense of manufacture of an imitation controlled substance if he or she knowingly manufactures with intent to deliver any imitation controlled substance.

2. The offense of manufacture of an imitation controlled substance is a class E felony.

(L. 2014 S.B. 491)
Effective 1-01-17

579.055. Manufacture of a controlled substance — penalties.

1. A person commits the offense of manufacture of a controlled substance if, except as authorized in this chapter or chapter 195, he or she:

(1) Knowingly manufactures, produces, or grows a controlled substance;

(2) Attempts to manufacture, produce, or grow a controlled substance; or

(3) Knowingly possesses a controlled substance with the intent to manufacture, produce, or grow any amount of controlled substance.

2. The offense of manufacturing or attempting to manufacture any amount of controlled substance is a class B felony when committed within two thousand feet of the real property comprising a public or private elementary, vocational, or secondary school, community college, college, or university. It is a class A felony if a person has suffered serious physical injury or has died as a result of a fire or explosion started in an attempt by the defendant to produce methamphetamine.

3. The offense of manufacturing or attempting to manufacture any amount of a controlled substance, except thirty-five grams or less of marijuana or synthetic cannabinoid, is a class C felony.

4. The offense of manufacturing thirty-five grams or less of marijuana or synthetic cannabinoid is a class E felony.

(L. 1989 S.B. 215 & 58, A.L. 1998 H.B. 1147, et al., A.L. 2003 S.B. 39, A.L. 2014 S.B. 491)
Transferred 2014; formerly 195.211; Effective 1-01-17

579.060. Unlawful sale, distribution, or purchase of over-the-counter methamphetamine precursor drugs — violation, penalty.

1. A person commits the offense of unlawful sale, distribution, or purchase of over-the-counter methamphetamine precursor drugs if he or she knowingly:

(1) Sells, distributes, dispenses, or otherwise provides any number of packages of any drug product containing detectable amounts of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts, optical isomers, or salts of optical isomers, in a total amount greater than seven and two-tenths grams to the same individual within a thirty-day period, unless the amount is dispensed, sold, or distributed pursuant to a valid prescription; or

(2) Purchases, receives, or otherwise acquires within a thirty-day period any number of packages of any drug product containing any detectable amount of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts or optical isomers, or salts of optical isomers in a total amount greater than seven and two-tenths grams, without regard to the number of transactions, unless the amount is purchased, received, or acquired pursuant to a valid prescription; or

(3) Purchases, receives, or otherwise acquires within a twenty-four-hour period any number of packages of any drug product containing any detectable amount of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts or optical isomers, or salts of optical isomers in a total amount greater than three and six-tenths grams, without regard to the number of transactions, unless the amount is purchased, received, or acquired pursuant to a valid prescription; or

(4) Sells, distributes, dispenses, or otherwise provides any number of packages of any drug product containing detectable amounts of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts, optical isomers, or salts of optical isomers, in a total amount greater than forty-three and two-tenths grams to the same individual within a twelve-month period, unless the amount is dispensed, sold, or distributed pursuant to a valid prescription; or

(5) Purchases, receives, or otherwise acquires within a twelve-month period any number of packages of any drug product containing any detectable amount of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts or optical isomers, or salts of optical isomers in a total amount greater than forty-three and two-tenths grams, without regard to the number of transactions, unless the amount is purchased, received, or acquired pursuant to a valid prescription; or

(6) Dispenses or offers drug products that are not excluded from Schedule V in subsection 17 or 18 of section 195.017 and that contain detectable amounts of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts, optical isomers, or salts of optical isomers, without ensuring that such products are located behind a pharmacy counter where the public is not permitted and that such products are dispensed by a registered pharmacist or pharmacy technician under subsection 11 of section 195.017; or

(7) Holds a retail sales license issued under chapter 144 and knowingly sells or dispenses packages that do not conform to the packaging requirements of section 195.418.

2. A pharmacist, intern pharmacist, or registered pharmacy technician commits the offense of unlawful sale, distribution, or purchase of over-the-counter methamphetamine precursor drugs if he or she knowingly:

(1) Sells, distributes, dispenses, or otherwise provides any number of packages of any drug product containing detectable amounts of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts or optical isomers, or salts of optical isomers, in a total amount greater than three and six-tenth grams to the same individual within a twenty-four hour period, unless the amount is dispensed, sold, or distributed pursuant to a valid prescription; or

(2) Fails to submit information under subsection 13 of section 195.017 and subsection 6 of section 195.417 about the sales of any compound, mixture, or preparation of products containing detectable amounts of ephedrine, phenylpropanolamine, or pseudoephedrine, or any of their salts, optical isomers, or salts of optical isomers, in accordance with transmission methods and frequency established by the department of health and senior services; or

(3) Fails to implement and maintain an electronic log, as required by subsection 12 of section 195.017, of each transaction involving any detectable quantity of pseudoephedrine, its salts, isomers, or salts of optical isomers or ephedrine, its salts, optical isomers, or salts of optical isomers; or

(4) Sells, distributes, dispenses or otherwise provides to an individual under eighteen years of age without a valid prescription any number of packages of any drug product containing any detectable quantity of pseudoephedrine, its salts, isomers, or salts of optical isomers, or ephedrine, its salts or optical isomers, or salts of optical isomers.

3. Any person who violates the packaging requirements of section 195.418 and is considered the general owner or operator of the outlet where ephedrine, pseudoephedrine, or phenylpropanolamine products are available for sale shall not be penalized if he or she documents that an employee training program was in place to provide the employee who made the unlawful retail sale with information on the state and federal regulations regarding ephedrine, pseudoephedrine, or phenylpropanolamine.

4. The offense of unlawful sale, distribution, or purchase of over-the-counter methamphetamine precursor drugs is a class A misdemeanor.

(L. 2014 S.B. 491, A.L. 2014 H.B. 1371, A.L. 2020 H.B. 1682 merged with H.B. 1896)

579.078. Possession of an imitation controlled substance — penalty.

1. A person commits the offense of possession of an imitation controlled substance if he or she knowingly possesses an imitation controlled substance.

2. The offense of possession of an imitation controlled substance is a class A misdemeanor.

(L. 1989 S.B. 215 & 58, A.L. 2014 S.B. 491)
Transferred 2014; formerly 195.241; Effective 1-01-17

579.080. Delivery of an imitation controlled substance — penalty.

1. A person commits the offense of delivery of an imitation controlled substance if he or she knowingly delivers, possesses with intent to deliver, or causes to be delivered any imitation controlled substance.
2. The offense of delivery of an imitation controlled substance is a class E felony.

(L. 1989 S.B. 215 & 58, A.L. 2014 S.B. 491)
Transferred 2014; formerly 195.242; Effective 1-01-17

579.082. Marketing of ephedrine or pseudoephedrine — penalty.

1. A person commits the offense of unlawful marketing of ephedrine or pseudoephedrine if he or she knowingly markets, sells, distributes, advertises, or labels any drug product containing ephedrine, its salts, optical isomers and salts of optical isomers, or pseudoephedrine, its salts, optical isomers and salts of optical isomers, for indication of stimulation, mental alertness, weight loss, appetite control, energy or other indications not approved under the pertinent federal over-the-counter drug Final Monograph or Tentative Final Monograph or approved new drug application.
2. The offense of unlawful marketing of ephedrine or pseudoephedrine is a class E felony.

(L. 1996 H.B. 1301 & 1298, A.L. 2014 S.B. 491)
Transferred 2014; formerly 195.248; Effective 1-01-17

579.084. Distribution of controlled substance in violation of registration requirements — penalty.

1. A person commits the offense of distribution of a controlled substance in violation of registration requirements if he or she:
   (1) Is subject to the provisions of sections 195.005 to 195.198, and knowingly distributes or dispenses a controlled substance in violation of section 195.030;
   (2) Is a registrant, and knowingly distributes or dispenses a controlled substance not authorized by that person's registration to another registrant or other authorized person; or
   (3) Knowingly refuses or fails to make, keep or furnish any record, notification, order form, statement, invoice or information required under section 195.050.
2. The offense of distribution of a controlled substance in violation of registration requirements is a class E felony when the offense is a violation of subdivision (1) or (2) of subsection 1 of this section.
3. The offense of distribution of a controlled substance in violation of registration requirements is a class A misdemeanor when the offense is a violation of subdivision (3) of subsection 1 of this section.

(L. 1989 S.B. 215 & 58, A.L. 2014 S.B. 491)
Transferred 2014; formerly 195.252; Effective 1-01-17

579.086. Unlawful delivery of a controlled substance by manufacturer or distributor — penalty.

1. A manufacturer or distributor, or an employee of a manufacturer or distributor, commits the offense of unlawful delivery of a controlled substance when he or she knowingly delivers a controlled substance while acting recklessly as to whether the controlled substance will be used in violation of this chapter.
2. The offense of unlawful delivery of a controlled substance by a manufacturer or distributor is a class E felony.

(L. 1989 S.B. 215 & 58, A.L. 2014 S.B. 491)
Transferred 2014; formerly 195.254; Effective 1-01-17

579.090. Tampering with a prescription or a drug prescription order — penalty.

1. Any pharmacist licensed under chapter 338 commits the offense of tampering with a prescription or a prescription drug order as defined in section 338.095 if such person knowingly:
   (1) Causes the intentional adulteration of the concentration or chemical structure of a prescribed drug or drug therapy without the knowledge and consent of the prescribing practitioner; or
   (2) Misrepresents a misbranded, altered, or diluted prescription drug or drug therapy with the purpose of misleading the recipient or the administering person of the prescription drug or drug therapy; or
   (3) Sells a misbranded, altered, or diluted prescription drug therapy with the intention of misleading the purchaser.
2. The offense of tampering with a prescription drug order is a class A felony.

(L. 2003 S.B. 5, A.L. 2014 S.B. 491)
Transferred 2014; formerly 565.350; Effective 1-01-17

579.115. Copy of suspicious transaction report for certain drugs to be submitted to chief law enforcement officer, when — suspicious transaction defined — penalty.

1. Any manufacturer or wholesaler who sells, transfers, or otherwise furnishes ephedrine, pseudoephedrine or phenylpropanolamine, or any of their salts, optical isomers and salts of optical isomers, alone or in a mixture, and is required by federal law to report any suspicious transaction to the United States attorney general, shall submit a copy of the report to the chief

law enforcement official with jurisdiction before completion of the sale or as soon as practicable thereafter.

2. As used in this section, “suspicious transaction” means any sale or transfer required to be reported pursuant to 21 U.S.C. Section 830(b)(1).

3. The offense of failure to report suspicious transactions is a class E felony.

(L. 2001 S.B. 89 & 37, A.L. 2014 S.B. 491)
Transferred 2014; formerly 195.515; Effective 1-01-17

Index

MISSOURI BOARD OF PHARMACY

STATUTE/RULE INDEX

(April 2023)

The Honorable Michael L. Parson, Governor

Chlora Lindley-Myers, Director
Department of Commerce and Insurance

Sheila Solon, Director Division of Professional Registration

Kimberly Grinston, Executive Director
Missouri Board of Pharmacy

ATTENTION:

The following general index is being provided for informational purposes only and is not conclusive. Additional federal or state laws may be applicable that are not listed in this document. Licensees review all governing statutes/rules in their entirety to ensure compliance with Missouri law. Official and complete versions of Chapter § 338, RSMo, Chapter 195, RSMo, and the rules of the Board may be found on the Board's website at www.pr.mo.gov/pharmacists.asp. Please be advised chapters 195, RSMo, and 19 CSR 30 governing controlled substances are under the jurisdiction of the Missouri Department of Health and Senior Services.

A

B

C

D

[1] Chapters 195 and 196 RSMo, and 19 CSR 30 governing controlled substances are under the jurisdiction of the Missouri Department of Health and Senior Services and the Missouri Bureau of Narcotics and Dangerous Drugs.

E

F

G

H

I

J

L

M

N

O

P

R

S

T

V

W